

Pursuing ESG in the Life Sciences Sector



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I. Introductory Letter

Kristy Balsanek and John Gilluly

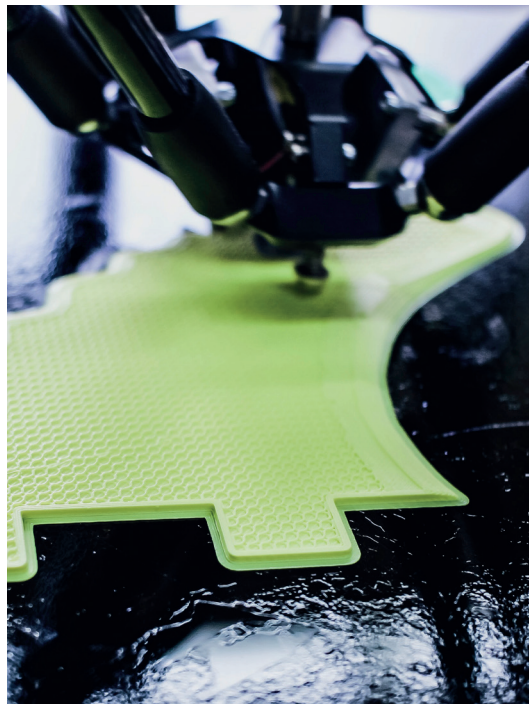
DLA Piper’s Life Sciences Sector, in partnership with The University of Texas Global Sustainability Leadership Institute (UTGSLI), is pleased to publish this Life Sciences ESG Handbook, the first of a series of sector-specific ESG handbooks, designed for global and domestic life sciences sector companies in the United States. We believe this handbook can be beneficial to life sciences companies of all sizes, ranging from large publicly held companies to those that are pre-commercial or otherwise have limited resources and budgeting. We also hope that this handbook helps policymakers, academics and other interested parties to understand better the topics of sustainability and ESG as they relate to the life sciences sector. See “About UTGSLI and DLA Piper” for more information about our partnership.

As discussed further in this handbook, consideration and effective management of social or “S” topics, such as bioethics, human capital management, product safety and access, and governance or “G” topics, such as board oversight of risks, are cornerstones of successful life sciences companies. Further, the life sciences sector depends on, among other “E” issues, an abundance and variety of natural resources.

In the last decade, our world has endured, and continues to endure, numerous events that directly or indirectly have profound impacts on the life sciences sector (eg, a global pandemic, climate change, global conflict, geopolitical tensions, cyberattacks and global supply chain disruptions and failures). These events vividly demonstrate the innumerable interdependencies and complexities in our world and show us that such events can no longer be treated as exogenous to a company and its purpose. Businesses and their leaders can expect in coming years that our complex, interdependent world will experience ongoing shocks that may be unpredictable and sometimes volatile and destructive.

Meanwhile, new technologies continue to disrupt businesses and change people’s lives in ways that

would have been hardly recognizable at the beginning of the millennium. Today, 2.5 quintillion bytes of new information are created each day, and the Internet of Things (IoT), artificial intelligence, blockchain and other new technologies seem to be accelerating the pace of automation and communication.




Companies within the life sciences sector must simultaneously plan for the long term while organizing and operating in ways that enable them to rapidly respond, adapt and innovate in our modern world. Those that do will have substantial advantages over others that expect or hope that our world will one day return to a steady and consistent operating environment and that are unwilling or unable to deviate from traditional theories of management and operational structure.

As we explain further in this handbook, incorporating ESG topics into both short- and long-term strategic planning and related initiatives and communicating progress on ESG and sustainability topics can help life sciences companies manage resources better, engage more effectively with stakeholders, and adapt to, and comply with changing (and often conflicting) regulations in the US and abroad. We and our partners at UTGLSI hope this handbook will provide some clarity and guidance on these complex topics and contribute to your company's success.

About UTGLSI and DLA Piper

The [University of Texas's Global Sustainability Leadership Institute](#) (UTGLSI) is an innovative cross-disciplinary research institute focusing on corporate sustainability, sustainable finance, impact innovation and infrastructure and sustainability communications. The mission of UTGLSI is to develop leadership and solutions that address critical sustainability challenges and shape an inclusive, regenerative global economy and society.

[DLA Piper](#) is a global law firm with lawyers located in more than 40 countries throughout the Americas, Asia Pacific, Europe, Africa and the Middle East. DLA Piper's Global Life Sciences Sector combines legal and regulatory experience with deep knowledge of the sector, including pharmaceuticals, medical devices, biotechnology, healthtech, clinical research services and the latest therapeutic innovations. Working across more than 50 jurisdictions, our Global Life Sciences



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Sector has handled cutting-edge life sciences matters such as the first mRNA vaccines, matters involving new cell and gene therapies, the use of artificial intelligence and machine learning in drug development, and the development of innovative applications in healthtech. Since early 2019, DLA Piper's United States ESG Data Analytics team, based in Austin, Texas, has worked with our Life Sciences Sector to collect information on the sustainability disclosures and practices of life sciences companies to provide data-driven ESG information to our clients. One of the most challenging facets of ESG is the lack of available data. We have partnered with the UTGLSI since 2022 to further investigate and present our learnings about ESG issues pertinent to the life sciences sector. More information about our datasets is available in Appendix I.

If you have any questions or comments regarding this publication, or questions that you would like us to answer in our next edition of the Life Sciences ESG Handbook or in future ESG publications, please do not hesitate to contact DLA Piper ESG Data Analytics at dlapipercorporatedataanalytics@us.dlapiper.com.

II. ESG Basics

What do we mean by “ESG”?

Brent Bernell, Brooke Goodlett, UTGSLI and DLA Piper ESG Data Analytics

“ESG,” which at its simplest, stands for “environmental, social and governance” is in practice an umbrella term for a wide array of potential topics that may be material to a company and its stakeholders, including investors, employees, customers, suppliers and members of its communities. Examples of ESG topics include climate change management and transition, reduction of a company’s carbon footprint and its overall impact on the environment, waste management, preventing deforestation and biodiversity loss, human rights issues, labor practices, employee health and safety, diversity and inclusion, product quality and safety, charitable initiatives and supply chain management. ESG can even include areas that stakeholders might not expect, such as cybersecurity and data privacy. ESG is about ongoing engagement – whether to identify and understand the topics that are material to a company, to measure the impact and results of various initiatives, or to communicate the results of the company’s efforts. The relevance of each of these subtopics, as well as related standards, norms and approaches, varies greatly from sector to sector, and even with respect to companies in the same sector.

ESG is not a fad or a new phenomenon, although it has and continues to evolve. The modern incarnation of ESG and the continuing efforts by many to compel related disclosure can be traced to the environmental activism and litigation of the 1970s. Before the term ESG was coined in an October 2005 United Nations Environmental report, the issues inherent in ESG were known by terms such as “environmental health and safety” or “EHS,” “corporate social responsibility” or “CSR,” “ethical capitalism,” “stakeholder capitalism,” and similar terms. Since then, the universe of ESG topics has expanded substantially, so its relevance has to be tailored to specific industries and companies. As mentioned in the introductory letter, the four main principles of bioethics- Autonomy, Beneficence, Nonmaleficence, and Justice – as originally described by Tom L. Beauchamp and James L. Childress, are central to the life sciences sector.

Bioethical concerns, as well as many ESG topics central to the life sciences sector, generally fall under the “S” or “G” categories of ESG.

For example, the Sustainability Accounting Standards Board, or SASB (now part of the International Sustainability Standards Board, or ISSB, and discussed further in Section IV.E (ESG Reporting Frameworks and Ratings), is an ESG framework designed to map the most financially material ESG issues on a sector-by-sector basis. SASB’s “Materiality Map”™ includes tailored key sustainability issues across six subsectors within the life sciences industry, and as illustrated by the word cloud below, the “S” and “G” topics, including “management” (which includes a broad range of

The modern incarnation of ESG and the continuing efforts by many to compel related disclosure can be traced to the environmental activism and litigation of the 1970s.

responsibilities, including supply chain management, energy management, product lifecycle management, and waste management) were most prevalent under SASB standards. While environmental concerns and climate transition often are primary in the broader discourse around ESG, what is most important for ESG-focused stakeholders differs from sector to sector and, in the life sciences sector, environmental concerns and climate transition, while important, are generally subordinated to “S” issues such as the principles of bioethics, product safety and access and “G” issues like ESG governance and management. That is why, for purposes of this handbook, we have “flipped” the acronyms to “SGE,” to emphasize the primacy of social and governance issues in the life sciences sector.



SASB ESG Issues in the Life Sciences Sector by Prevalence

The 2019 Business Roundtable Statement on the Purpose of a Corporation and ESG's Philosophical Underpinnings

John Gilluly

As we noted in the previous Section II.A. “What Do We Mean by ‘ESG?’” the modern incarnation of ESG and the continuing efforts by many to compel related disclosure can be traced to the environmental activism and litigation of the 1970s. Companies today are grappling with increasing stakeholder demand for ESG commitments and reporting and increasing global ESG regulation. Historically, however, ESG strategy has primarily been voluntarily, and regulatory reform, particularly in the United States, has been slow in part because the movement is heavily rooted on the premise that our Adam Smith-style capitalist system should be changed to better shape our world. As a result, the ESG debate is often cast as a referendum on the purpose of corporations and shareholder primacy.

In simplistic terms, some ESG proponents argue that capitalism in its current form fails to live up to societal values and should be modified to require that corporations and their leaders prioritize the needs of a broader set of stakeholders than just shareholders. These proponents point to the large body of environmental damage, inequality and other evidence that corporations do not sufficiently consider ESG topics and that corporations and their leaders would do less harm and drive positive change if properly incentivized.

Some ESG detractors argue that the purpose of for-profit corporations (and, by extension, their greatest benefit to society) is to create value and that we should not modify capitalism or target public companies to impose alternative values on them unless failure to do so would be detrimental to shareholders. In other words, to create long-term value for shareholders, a corporation must effectively manage the interests of its broader group of stakeholders, so accountability to shareholders and allocation of capital are the best measures and influencers of that effectiveness.

While these concepts may seem antiquated, the debate over shareholder primacy still rages today. In August 2019, the Business Roundtable (BRT), which since 1997, endorsed the principles of shareholder primacy, issued a revised [Statement on the Purpose of a Corporation](#), signed by the CEOs of 181 leading public companies, including most of the world’s largest pharmaceutical companies. Specifically, these CEOs committed to (in order):

- “Delivering value to our customers. We will further the tradition of American companies leading the way in meeting or exceeding customer expectations.

- Investing in our employees. This starts with compensating them fairly and providing important benefits. It also includes supporting them through training and education that help develop new skills for a rapidly changing world. We foster diversity and inclusion, dignity and respect.
- Dealing fairly and ethically with our suppliers. We are dedicated to serving as good partners to the other companies, large and small, that help us meet our missions.
- Supporting the communities in which we work. We respect the people in our communities and protect the environment by embracing sustainable practices across our businesses.
- Generating long-term value for shareholders, who provide the capital that allows companies to invest, grow and innovate. We are committed to transparency and effective engagement with shareholders."

Few would argue against the noble intentions behind these commitments, but the BRT statement was

regarded by many as fundamentally inconsistent with the fiduciary duties of directors and officers and a direct assault on shareholder primacy.

The Council of Institutional Investors (CII) promptly issued a [rebutal](#) of the BRT's expansion and prioritization of corporate obligations. While acknowledging the role that businesses play for employees and communities, the CII reaffirmed the institutional investment community's position that long-term shareholder value creation and the efficient allocation of capital are the root drivers of value creation and delivery across all stakeholders.

The events of the last few years have not reduced the pressure on companies to take a broader view of their purpose and mission, and Sections II.C ("Why is ESG Important? Activism, Shareholder Proposals and Governance Engagement") and II.D ("Why is ESG Important? Other Stakeholders and Regulations") explain why ESG has grown in importance in recent years.

Why Is ESG Important? Activism, Shareholder Proposals and Governance Engagement

Emilio Ragosa, Brooke Goodlett and DLA Piper ESG Data Analytics

TYPES OF ESG ACTIVIST INVESTORS

The increasing investment in ESG funds, by both institutional and retail investors, explained more in Section VIII.A ("ESG Finance"), as well as an increasing interest in sustainability among retail investors, has led to the rise of the ESG shareholder activist. There are three main types of ESG activist investors:

- The "governance-minded" investor
- The "ESG fund" investor
- The "social agenda" investor

The "governance-minded" investor represents traditional asset managers, including state pension and retirement funds. Their main concern is economic growth, in the short- or long- term, depending on their investment strategy. An increasing number of these traditional asset managers have determined that decarbonization is the way of the future and have signed onto commitments such as the Net Zero Asset Manager's Initiative, which currently has 301 signatories, including some of the

largest global asset managers. These asset managers have committed to achieve net zero alignment by 2050 or sooner across all Assets Under Management (AUM). To achieve these goals, these asset managers are demanding data regarding a company's environmental footprint and making investment decisions accordingly. Additionally, these traditional asset managers have been calling for gender and racial or ethnic diversity on boards of directors and, more recently, in the workforces, of the companies they invest in.

Several "governance-minded" investors, in accordance with their stated voting guidelines, have voted against heads of the nominating and corporate governance committee or other board members where they find a portfolio company's attention to ESG or voluntary ESG disclosure lacking. While these investors tend to vote against shareholder proposals demanding more disclosure or radical changes to how the company does business, they may be persuaded by "ESG fund investors" or "social agenda" investors to support

The life sciences sector has not been immune to the trend of increased activism and has seen ESG activism, most notably in the “S” space – such as shareholder proposals pursuing gender equality and social justice, rights and equity.

shareholder proposals or other activism campaigns when they feel that companies are not responding to their requests for ESG data or engagement. Additionally, proxy advisory firms have adopted ESG-related voting guidelines, and if a company draws such a negative vote recommendation from ISS and/or Glass Lewis, these traditional asset managers may follow the vote recommendation and vote against the chair or members of the nominating and governance committee.

Like the governance-minded investor, the ESG fund investor, or, as they have historically been called, the “socially responsible investor,” is also concerned with economic growth- in the short- or long- term, depending on their investment strategy. However, they pursue ESG as a goal in itself, of equal or greater importance to economic growth. There are two subcategories of “ESG fund” investors: the ESG metrics investor and the impact investor. An ESG metrics investor has similar concerns as a traditional governance-minded asset manager but will solely invest in companies that meet certain ESG metrics set by the fund. Some ESG funds invest in companies with certain ESG or diversity scores under certain methodologies, while others invest in “green tech” or other “green” industries, or avoid investing in the fossil fuels industry, weapons manufacturers or other industries which have, in their eyes, a negative social impact. The impact ESG fund investor operates a fund that has a stated goal of generating change, in particular, a positive social impact, and may utilize activist strategies to ensure that their impact goals are met. The ESG fund investor is looking for investment opportunities that meet their fund goals and may make significant investments in companies that they believe will deliver both a positive return to investors and society at large.

The “social agenda” investor is one who will take a nominal stake in a company to pursue a particular political or social aim. These include non-profits, retail investors and members of the clergy. While these

investors generally take a small stake in a company individually, they might partner with governance-minded investors and ESG fund investors to pursue a weak target that they feel is ripe for a change. In a major shake-up in the corporate world in 2021, investors ousted board members from a major energy and natural resources company due to concerns about insufficient oversight of the company's climate transition and decarbonization plans.

FACTORS DRIVING INCREASED ACTIVISM

With the power of social media, activist investors are able to coordinate and disseminate information faster and broader than ever. Additionally, these investors have the support of the Securities Exchange Commission (SEC) more than ever before, given:

- the SEC's new universal proxy rules, which went into effect in August 2022, and mandates that, under certain circumstances, the company must include dissident director nominees on its proxy card, and
- its November 2021 Staff Bulletin No. 14L, which rescinded prior SEC staff legal bulletins and outlined new views on Rule 14a-8(i)(7), the ordinary business exception, and Rule 14a-8(i)(5), the economic relevance section, which views closed the door to excluding many social and environmental proposals from inclusion in a company's proxy statement under these exceptions. “For example,” the SEC staff wrote, “proposals raising squarely human capital management issues with a broad societal impact would not be subject to exclusion solely because the proponent did not demonstrate that the human capital management issue was significant to the company.”

Companies should be mindful of how these developments, as well as the overall trend of increased activism, may impact the company. Several companies have proactively adopted bylaw changes to address the new universal proxy rules.

SHAREHOLDER PROPOSALS

Topics Raised

The life sciences sector has not been immune to the trend of increased activism and has seen ESG activism, most notably in the “S” space – such as shareholder proposals pursuing gender equality and social justice, rights and equity. From January 2021 to August 2022, the DLA Piper Data Analytics Team analyzed 344 shareholder proposal campaigns, 29 of which regarded the life sciences and health sector, roughly 8% of the 344. Note that a great deal of shareholder activism may not be reflected in these statistics because the company and the shareholder activist negotiate a compromise position that is adopted by the company without having to submit a shareholder proposal. From these life sciences and health sector campaigns, five key topics accounted for 87.9% of the topics covered. These were:

- Lobbying (27.3%)
- Politics (24.2%)
- Health (12.1%)
- COVID-19 (15.2%)
- Gender (9.1%)

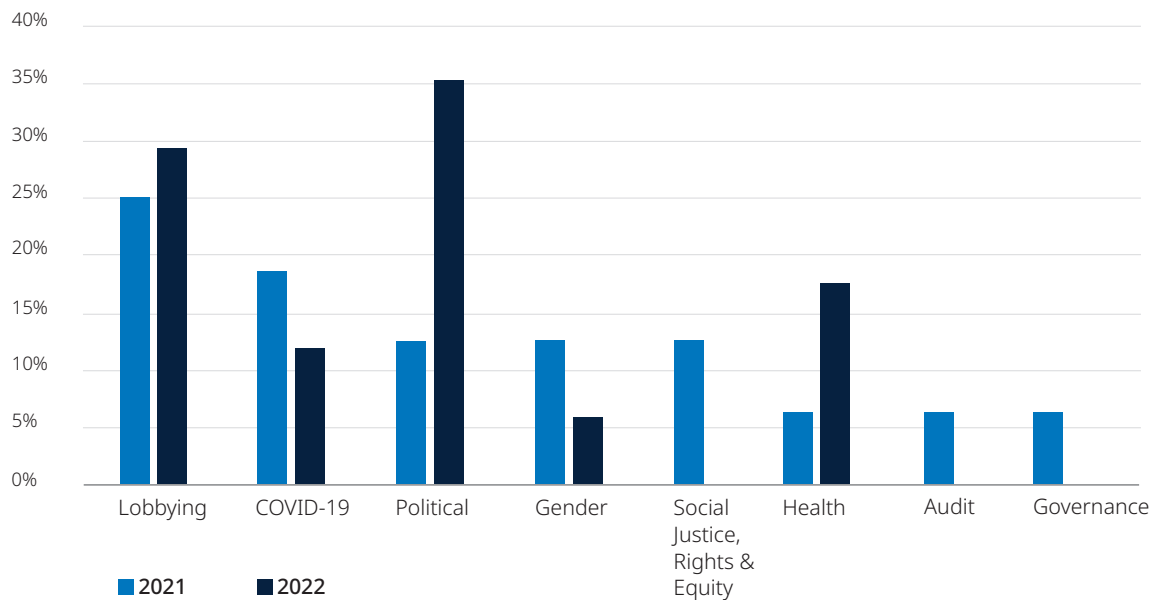
The remaining 12.1% included social justice, rights, & equity, governance, and audit matters. From 2021 to 2022, there was a significant consolidation of key topics concerning the campaigns. In 2021, the campaign topics involved:

- Lobbying (25%)
- COVID-19 (18.75%)
- Political (12.5%)
- Gender (12.5%)
- Social Justice, Rights, & Equity (12.5%)
- Health (6.25)
- Audit (6.25%)
- Governance (6.25%)

In 2022, the campaign topics shifted to:

- Lobbying (29.4%)
- COVID-19 (11.8%)
- Political (35.3%)
- Gender (5.9%)
- Health (17.6%)

Campaign Topics 2021–2022



When comparing the life sciences sector to a more general review of the 2021-2022 Shareholder Proposal season, both analyses have more in common than not, such as emphasis of ESG, social justice issues, and traditional governance issues.

Rationale for Campaigns


An interesting trend observed in the 2022 proxy season was activist groups with differing agendas bringing similar campaigns for different reasons. For example, some large pharmaceutical companies received stockholder proposals seeking greater scrutiny of a company's racial equity practices, but one on the grounds that the company was not doing enough in terms of fostering racial equity in its workplace ("traditional ESG rationale"), while another proposal sought the same on the ground that the company was improperly mandating racial discrimination against White, male employees ("non-traditional ESG rationale"). Of the campaigns studied in the life sciences sector, in 2022, 12% adopted non-traditional ESG rationale, 69% adopted traditional ESG rationale and 19% were neutral. In contrast, in 2021, 0% of ESG-related proposal campaigns in the life sciences sector adopted non-traditional ESG rationale.

Success Rates

In both 2021 and 2022, there were four health sector campaigns that resulted in an approval from shareholders. Of the campaigns that were denied, only five of them had "Yes" votes accounting for more than 40% but less than 50% of votes. Three of these campaigns were from 2021 with the other two were announced in 2022. A common trend amongst them is that four out of five of these close-call campaigns were relating to Lobbying, and the fourth, from 2022, referenced a political topic.

ENGAGING WITH ACTIVISTS

Even if a compromise is reached, shareholder activism campaigns distract management and consume resources that could be better spent executing the company's business priorities, and it is wise to protect against this threat. The most important way a company can protect itself from an activism campaign is to actively manage and report on their ESG strategy and be prepared to deliver specific information about the ESG



Even if a compromise is reached, shareholder activism campaigns distract management and consume resources that could be better spent executing the company's business priorities, and it is wise to protect against this threat.

issues material to the company and its investors, the company's ESG goals and progress towards those goals, and how the company oversees ESG matters. Companies that wait until shareholders bring up these concerns will be fighting off of their back foot. Secondly, the company should engage with investors, employees and other stakeholders on a regular basis – not just during proxy season – to understand their concerns and be familiar with the voting policies and priorities of its major shareholders. Some ways a company could engage with investors include hosting an ESG themed investor day or an ESG roadshow, or regularly addressing ESG on investor calls.

If a company receives a letter or request for ESG-related information from a non-profit or small stockholder, particularly those who have previously conducted shareholder activism campaigns, understand that this may be the first step in a series of events that could escalate into a shareholder activism campaign. Boards and management may want to conduct preparedness sessions and tabletop exercises to prepare for its response to an activism threat. Having a strategy prepared and appropriate resources to respond to these requests is crucial for organizations to correctly manage an activism threat.

Why Is ESG Important? Other Stakeholders and Regulation

Gwen Keyes Fleming, Teresa Hitchcock, Brooke Goodlett and UTGSLI

As mentioned in Section IV.C (“ESG Definition Disclosure Analysis”), we have seen exponential growth in voluntary corporate ESG disclosures and 92% of the 40 life sciences companies we analyzed in 2022 mention ESG in either their proxy statements or in sustainability reports. There are two main forces driving the exponential growth we’ve seen in voluntary ESG disclosures over the last 5 years:

1. pressure from stakeholders, in particular:

- **investors** – as we discuss above in “Why Is ESG Important? Activism, Shareholder Proposals and Governance Engagement” companies are receiving pressure from not only activist investors but also major asset managers,
- **customers, suppliers, and other value chain participants** – who are increasingly asking companies to make certifications related to a company’s ESG practices, and
- **employees** and

2. increased regulatory attention.

Changing global regulations have impacted how some companies think about environmental sustainability, human rights, and labor practices within their value chains. Business partners, potential investors and potential acquirers are more interested in understanding the environmental sustainability, social responsibility and ethical practices from the beginning to end of the life cycle of a company’s products and services.

For example, in the United States, we are seeing increased regulatory interest in both environmental (“E”) and social (“S”) practices of companies. The Biden administration has made climate change a priority by proposing rules that mandate disclosure of climate risks, governance practices and greenhouse gas (GHG) emissions by public companies (including smaller reporting companies) and mandating GHG reporting for federal contractors. See [our client alert](#) for more information regarding the substance of the proposed SEC climate change rules, as well as [our client alert](#) regarding how companies can prepare for climate transition. Additionally, companies may see increased

climate regulation at the US state level. For example, the State of California has attempted to pass aggressive regulations going beyond of the scope of the SEC’s proposed rules. The California Corporate Accountability Act, which would have mandated reporting and disclosure of Scopes 1, 2 and 3 emissions data by companies with total annual revenues in excess of a billion dollars that do business in California, failed to pass the California legislature on August 31, 2022. This law, if passed, would have required companies to report on and understand GHG emissions up and down their supply chain. The fact that the aggressive California Corporate Accountability Act failed this legislative session does not mean that the issue has been settled- we may see this bill or similar versions of it appear in future years, particularly if climate change becomes a more pressing political issue.

With regard to social (“S”) regulation, on the US federal level, the Uyghur Forced Labor Prevention Act, which became law on December 23, 2021, widened the ban on imported goods produced using forced labor under Section 307 of the Tariff Act of 1930. This act came into force on June 21, 2022, and prohibits any goods produced in the Xinjiang Uyghur Autonomous Region from entering the US unless the Commissioner of US Customs and Border Protection (CBP) grants an exception. Essentially, companies must rebut the presumption that all goods produced in this region are produced using forced labor in order to import any good from Xinjiang. Further, goods produced outside of the Xinjiang region will also be restricted from entry if any raw materials that were used to produce the finished good came from Xinjiang. This act has required companies, including private companies, and especially those relying on manufacturing operations in China for materials, to conduct extensive supply chain management mapping. At a state level, the California Transparency in Supply Chains Act of 2010 has increased efforts to prevent slavery and human trafficking in supply chains. The main purpose of this act is to heighten consumer understanding of trafficking occurrences in supply chains. The law applies to any company conducting business in California with an annual gross revenue over \$100 million; thus, even private companies are accountable under the law.

Spotlight on CSRD

The CSRD requires **all large companies** - meaning companies with more than 250 employees and more than €50 Million in turnover and/or more than €25 Million in total assets – and **all listed companies** (except micro-enterprises, less than 10 employees or below €20M in turnover) to report on their sustainability.

Under the CSRD, nearly **50,000 companies (15,000 in Germany alone) in the EU will need to follow detailed EU sustainability reporting standards**, corresponding to 75% of all EU companies' turnover.

WHICH INFORMATION WILL HAVE TO BE DISCLOSED?

Additional to the Non-Financial Reporting Directive (NFRD) Under Directive 2014/95/EU, large companies have to publish information related to:

- Environmental protection
- Social responsibility and treatment of employees
- Respect for human rights
- Anti-corruption and bribery and
- Diversity on company boards

Also, the CSRD is **adding additional requirements on:**

- **Double materiality concept:** It includes sustainability risks (like climate change) that affect the company and the company's impact on society and the environment.
- Companies will need to report on their process of selecting material topics for stakeholders.
- More **forward-looking information**, such as targets and progress, must be included in reports.
- Companies must disclose information relating to **intangible assets**, like social, human, and intellectual capital.
- Reporting in line with **Sustainable Finance Disclosure Regulation (SFDR)** and the **EU Taxonomy Regulation**.

- Businesses will correspondingly have to start reporting **how sustainability risks might affect their performance**.

While the EU provides voluntary reporting guidelines for NFRD reports, the CSRD introduces more detailed reporting requirements and requirements to report according to mandatory EU sustainability reporting standards. The CSRD reporting will align with the already existing [Sustainable Finance Disclosure Regulation](#) and the EU Taxonomy.

LEARN MORE ABOUT THE EU TAXONOMY WITH PLAN A'S WHITEPAPER.

What are the next steps?

On 28 November 2022, **the European Union Council gave its final approval to the corporate sustainability reporting directive (CSRD)**. Following the Council's approval of the European Parliament's position, the CSRD legislative act is adopted.

After being signed by the President of the European Parliament and the President of the Council, it was published in the [Official Journal of the European Union](#) and has entered into force on 5 January 2023. The new rules will need to be implemented by member states **18 months** later. Here is a timeline of the process since the CSRD entered into force, including the next steps and what to expect:

- **End of 2023:** EU Member States adopted the EU Directive into national law.
- **January 1, 2024:** Companies within the scope of CSRD and currently reporting under the NFRD are obliged to report their FY 2024 data in 2025. As of the beginning of 2024, all other large EU companies within the scope of CSRD are obliged to report.
- **January 1, 2025:** Businesses already subject to the NFRD will have to start reporting in the financial year 2024.
- **January 1, 2026:** SMEs listed on a regulated market (no micro-enterprises) obliged to report for FY 2025 (but under less stringent reporting requirements).
- **January 1, 2028:** Small and medium enterprises and small and non-complex credit institutions, and captive insurance undertakings will have to start reporting for the financial year 2027 - with a further possibility of voluntary opt-out until 2028. The reporting standards for SMEs will be lighter.
- **January 1, 2029:** Non-European companies that have branches or subsidiaries in the EU with a net turnover of €150M in the EU will have to report.

It requires these companies to publicly disclose their efforts to protect human rights in the supply chain along five dimensions of verification, auditing, certification, internal accountability, and training. The disclosures must be conspicuous and easily accessible on the company's website.

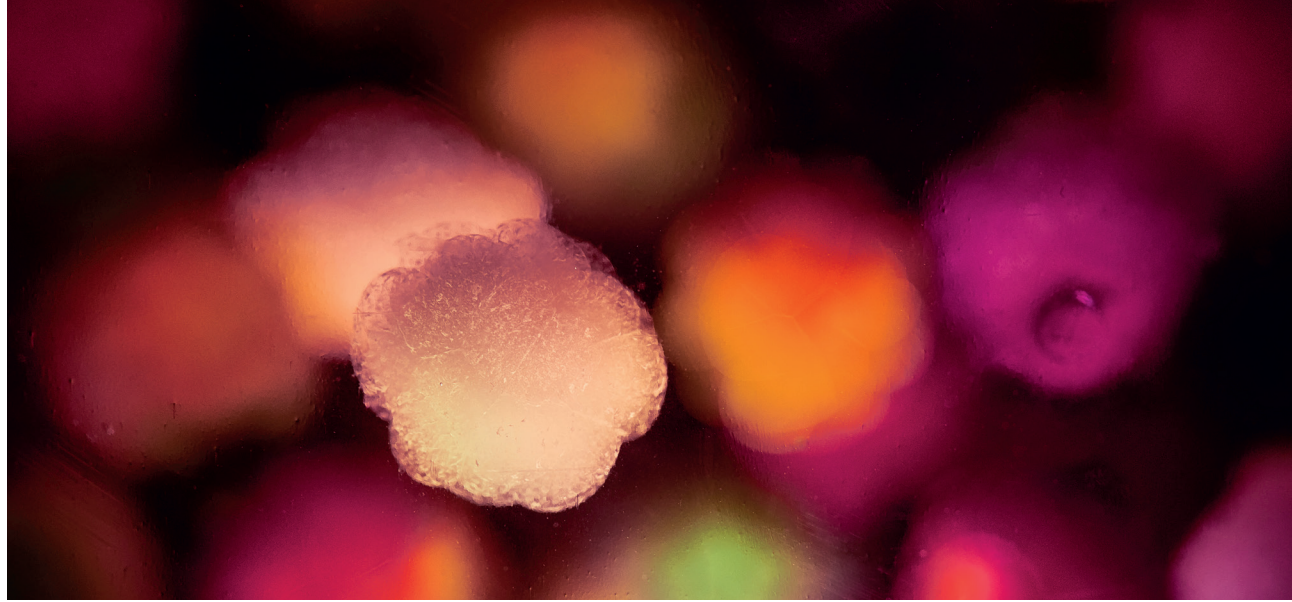
Internationally, the European Union and the United Kingdom have taken significant steps to regulate corporate sustainability and responsibility. Sectoral legislation has been in force for many years in the EU on Conflict Minerals and Timber. In 2015 the United Kingdom adopted the Modern Slavery Act which requires large commercial organisations (those with an annual global turnover of £36m or more, wherever incorporated or formed) to publish a statement setting out the steps they are taking to prevent modern slavery in their supply chains. In 2017 France adopted the 'Law of Vigilance' which has been in force for some time. This requires all large French companies (with over 5,000 employees in France or over 10,000 worldwide) to develop and implement a vigilance plan to identify and prevent violations of fundamental rights, health and safety of people, and the environment, with sanctions in case of non-compliance. In June 2021 Germany adopted a Supply Chain Due Diligence Law, called Lieferkettensorgfaltspflichtengesetz or LkSG, requiring large companies to identify, assess, prevent and remedy human rights and environmental impacts in their supply chains and operations, with fines of up to 2% of annual revenues in case of non-compliance. This law came into effect January 1, 2023 and applies to companies based in Germany or German-registered branches of foreign companies with more than 3,000 employees, and from 2024 to similar companies with more than 1,000 employees. Similar legislation is in the pipeline in other Member States. The EU's Corporate Sustainability Reporting Directive (CSRD) approved on November 28, 2022, together with both the existing EU Taxonomy Regulation and associated delegated acts have far-reaching effects that impact public and private companies inside and outside of the EU who will be responsible for reporting under the CSRD in certain circumstances. Additionally, public and private companies operating entirely outside of the EU that compete with or are part of the value chains of CSRD-reporting companies may face increased commercial pressure to report on sustainability practices. Additionally, in the UK there are already mandatory

requirements for reporting on climate-related risks and actions for large companies.

On June 1, 2023, the European Parliament adopted proposed text for a Directive on Corporate Sustainability Due Diligence which is applicable to regulated companies' entire value chain (upstream and downstream). The next step in passing the Directive is a "Trialogue" negotiation process to resolve the differences between differing proposals, which is expected to conclude in 2024. Once officially adopted, the Directive will be transposed into domestic laws within two years by EU member states. In addition, individual countries in Europe and the United Kingdom have regulated supply chain sustainability and promoted sustainable supply chains in their national healthcare systems. Sweden is considering a new environmental price premium for its national reimbursement system, and Germany have passed laws to curtail human rights and environmental abuses within large company's global supply chains, including in its healthcare system. In the United Kingdom, the National Health Service, or NHS, intends to become the world's first net zero national health service and has a Net Zero Supplier Roadmap and the NHS Supply Chain Master Services Agreement.

Implementation of these measures by companies operating globally will not be made easier in the context of competing government policies relating to security of supply of energy and other essential supplies, in response to recent emergencies such as the COVID-19 pandemic and the war in Ukraine. These are reflected for example in the recent EU proposal for a Single Market Emergency Instrument which would give the EU Commission new powers to require the stockpiling of critical goods and the prioritization of certain orders.

Even if the proposed EU corporate sustainability due diligence directive or the SEC's proposed climate disclosure rules are never adopted or are materially curtailed, we expect pressure from investors, value chain participants, customers and employees for increased ESG governance and disclosure to continue, particularly for global companies. Life sciences companies with robust sustainability and human rights governance may be able to distinguish themselves in the global marketplace and be more prepared to comply with the changing regulatory landscape.



Life Sciences Roundtables, Standards and NGOs

Andrew Gilbert, Brooke Goodlett and UTGSLI

The “alphabet soup” of sustainability frameworks, which is discussed in more detail in Section IV (“Governance”), is a frequent topic of discussion in ESG circles. While sustainability frameworks are important, management and ESG teams at life sciences companies may find more relevant information about ESG practices and trends from sector-specific roundtables, international standards and non-governmental organizations (NGOs). Below are some of the more well-known roundtables, international standards and NGOs applicable to the life sciences sector, and how they can assist a company in identifying and furthering its ESG goals.

- **BioPharma’s Investor ESG Communications Initiative**

The BioPharma Sustainability Roundtable, a platform for senior biotech and pharmaceutical executives to drive sustainability agendas, created this updated set of guidelines for leading BioPharma companies and investors in achieving more effective, efficient, and decision-useful communications about the sector’s most important ESG topics. BioPharma companies can use this initiative to prioritize ESG concerns and communicate more effectively with investors.

- **Center for International Organizations of Medical Science (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans**

CIOMS is an international NGO established in 1949 who works with the World Health Organization to develop a set of international ethical guidelines to provide answers for research ethics issues and to provide special guidelines in low-resource settings and how to involve vulnerable groups and use biological samples and health-related data for research. The first

version of the guidelines was prepared in 1982, and the standards are based on a number of international declarations, reports and guidance documents, like the Universal Declaration of Human Rights of the United Nations (1948) and the Universal Declaration on Bioethics and Human Rights of UNESCO (2005) as well as existing ethical frameworks, ethical papers and journals, such as the American Journal of Bioethics. Life sciences companies can use the guidelines to prioritize their research and practices, particularly when they are working on a budget with insufficient resources. Through these guidelines, companies can also get a more accurate depiction of findings by accounting for the conditions the research was conducted in.

- **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) – E6 Guideline for Good Clinical Practice**

ICH creates efficacy guidelines concerned with the design, conduct, safety and reporting of clinical trials, and novel types of medicine derived from biotechnological processes and the use of pharmacogenetics/pharmacogenomics techniques to produce better targeted medicines. ICH created these updated sets of guidelines as the blueprint for clinical trials ensuring subject safety and data quality. The guidelines specify the processes needed for study conduct and documentation to comply with the guideline and regulatory requirements. Life sciences companies can use this guideline to improve transparency, mandate ethical consideration when conducting a research project, and guarantee the satisfaction of research subjects.

- **International Federation of Pharmaceutical Wholesalers (IFPW) ESG Framework**

IFPW's ESG framework is an industry initiative which identifies twenty opportunities within six priority areas under each of Environmental, Social and Governance. The priority areas are: carbon footprint and climate, environmental stewardship, access to medicine, human capital management, board commitment and ethics, compliance and engagement.

- **Pharmaceutical Research and Manufacturers of America (PhRMA)'s Principles on Conduct of Clinical Trials and Communication of Clinic Trial Results**

PhRMA's principles consist of guidelines in order to clarify subjects and members' relationship with others involved in the clinical research process, to protect research participants, manage conduct of clinical trials, ensure objectivity in research, limit disclosure of clinical trial results, expand access to investigational drugs and enhance diversity in clinical trial participation. By following these principles, life sciences companies could improve their relations with subject groups and be transparent as well as protective with their research and its findings.

- **Sustainable Medicines Partnership**

The Sustainable Medicines Partnership, or SMP, is a not-for-profit private-public collaboration of 30

organizations, including leading pharmaceutical manufacturers, packagers, distributors, and others central to the medicine supply chain, as well as hospitals, academia, patient groups, and policymakers. The goal of SMP is to reduce pharmaceutical manufacturing waste, pharmaceutical packaging waste and medicine waste, and to better inform consumers about the shelf-life of medicine.

- **World Medical Association – Declaration of Helsinki**

The World Medical Association created this declaration as a statement of ethical principles or guidance for physicians during medical research involving human subjects, including research on identifiable human material and data. Physicians, under the Declaration of Helsinki, need to prioritize the subjects' well-being, best interest, privacy and rights, and obtain informed consent. While the Declaration is directed primarily to physicians, employing the use of the Declaration of Helsinki in any form of medical research involving human subjects may save many life sciences companies from being accused of ill treatment of research subjects, but also guarantee the safe treatment of vulnerable groups that are being studied. These companies can improve the results of their research by creating a safe and ideal environment for their subjects.

The Million-Dollar Question: Is ESG about Value, or Values?

Christina Houston, Brooke Goodlett and Noah Schottenstein

Are companies that invest in ESG more profitable than those who don't? This is the million-dollar or, perhaps more accurately, multi-trillion-dollar question. Whether ESG investing strategies will pay off in the future, and on what time frame, it depends on whom you ask, what data they use and how they analyze the data. ESG is rife with data challenges – including data that is unstandardized, unreliable, difficult to collect and/or housed in different silos of a company or even outside of the company. Information about scope 3 GHG emissions and sustainability practices, in particular, is generally controlled by third parties up and down the company's value chain and can be difficult to collect and verify. These data challenges are a major reason for the Biden SEC's call for mandated GHG emissions reporting. In addition to these data challenges, there

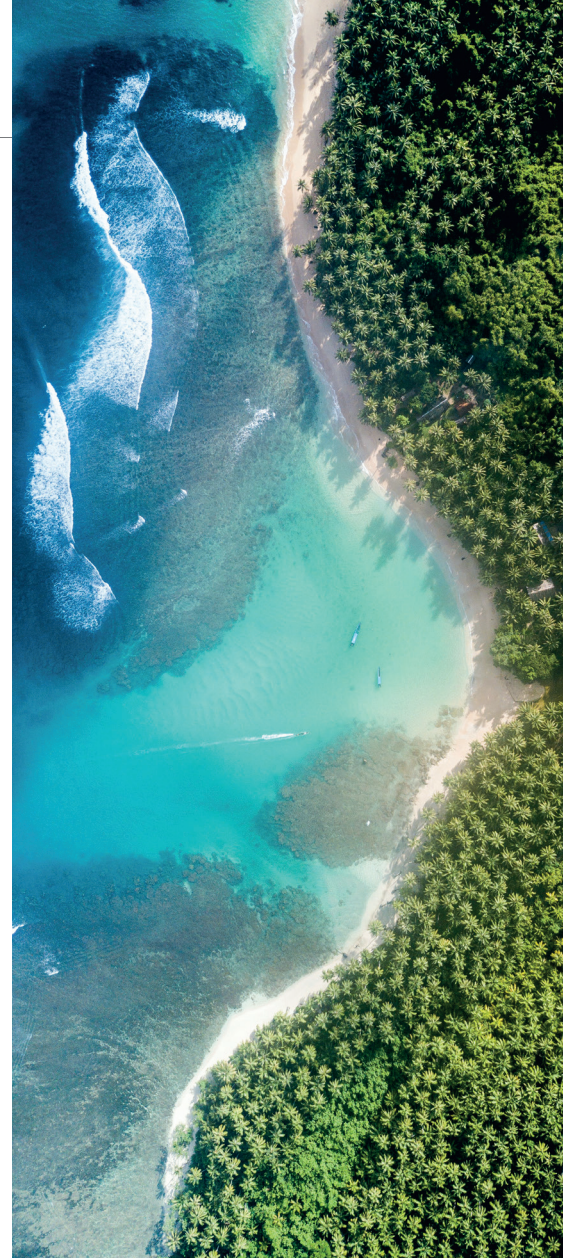
are many different measures of profitability: short term profitability, long term profitability and future projections about profitability relying on assumptions and hypotheses. As ESG critics like Vivek Ramaswamy note, these data challenges create an opportunity for analysts, academics, consultants, executives and others to cherry-pick ESG data to fit a particular agenda or narrative.

Notwithstanding these challenges, ESG investors are betting that a company's ESG investments will create long-term value and that companies that invest in sustainability and ESG initiatives will be better prepared to deal with climate-related physical risks, climate transition risks and rising carbon prices, and that these and other ESG investments will eventually pay off in the form of improved relationships with the company's

employees, customers, business partners and other key stakeholders. Ramaswamy notes that arguments promoting ESG for its correlation to long-term value are not arguments for *stakeholder* capitalism, but simply *traditional* capitalism, with an eye to profitability on a longer timeline. However, for some investors, traditionally called “socially responsible investors,” ESG may be an end in itself. Socially responsible investors are willing to accept potentially lower rates of return to ensure the companies they invest in create a positive social impact or avoid harmful social impacts. For some investors and other stakeholders, like values-driven employees or socially responsible investors, ESG is about a company’s *values*. For others, ESG is about the company’s *value*, particularly value over the long term. For many investors and other stakeholders, ESG is about both.

While being good stewards to the environment and society might make sound business sense, particularly in the long term, officers and directors of for-profit corporations generally only owe fiduciary duties to the corporation and its stockholders.

As described further in Section IV (“Governance”), resources permitting, engagement with a company’s stakeholders, particularly its investors, conducting materiality assessments and conducting competitive studies and peer group analysis can inform a company’s ESG mission and story. While being good stewards to the environment and society might make sound business sense, particularly in the long term, officers and directors of for-profit corporations generally only owe fiduciary duties to the corporation and its stockholders. ESG decisions should be made with the best interest of the company and its investors in mind. Officers, directors and management may face increasing pressure from “social agenda investors,” values-driven employees or other stakeholders to make environmental, social or political commitments,



investments or statements, or to take certain actions to promote a particular environmental, social or political cause. Companies that maintain open and frequent lines of communication with their investors and other stakeholders, and not just those actively engaging with the company on ESG, who have conducted a materiality assessment, and/or have conducted competitive studies and peer group analysis and have used these tools to inform a clear ESG mission, might be better prepared to respond to these demands in a thoughtful and deliberate manner. For profit companies, and especially those managing limited resources, need to balance the interests of differing stakeholders and the company’s mission critical initiatives and financial health should be its lodestar.

Leaders in Life Sciences ESG: Jennifer Prioleau, Senior Vice President, Chief Legal Officer and Chief Compliance Officer, B. Braun Medical Inc.



BIOGRAPHY

Jennifer Prioleau is Chief Legal Officer, Chief Compliance Officer and Corporate Secretary at B. Braun, the largest privately held global medical device and pharmaceutical company. In this role, she oversees B. Braun's legal and compliance functions and is now spearheading major strategic initiatives including, among other business and financial goals, driving ESG strategy and transforming the company into a technology company that can solve and simplify healthcare complexities to revolutionize patient care.

WHAT DO YOU THINK ARE THE MOST PRESSING ESG ISSUES FACING THE LIFE SCIENCES INDUSTRY?

Environmental

The largest environmental sustainability issue the life sciences industry faces is improving the sustainability of medicines and medical devices while reducing greenhouse gas emissions. For B. Braun, environmental issues are significant given our substantial in-house manufacturing and complex supply chains.

Social

Social or "S" issues are particularly central to the life sciences industry, especially product social impact and health equity.

Naturally, life sciences companies focus heavily on the inherent "ESG-positive" quality of their products to improve the public health. B. Braun's products and purpose play a crucial role in protecting public health, which creates real societal value, which is why I joined B. Braun. Looking beyond products and purpose, I am now focusing my efforts on driving ESG strategy in a way that is meaningful and relevant for our various stakeholders: customers, partners, employees, shareholders and regulators.

Promoting inclusion and equity and health care and unbiased treatment of patients is a key ESG concern of the life sciences industry, and this requires partnerships to educate the industry and others on identifying, acknowledging, and addressing bias. This

includes partnering in education with stakeholders, such as partnering with clinicians to educate them regarding disparate trends in patient care, including access to technologies. Promoting health equity also includes advocating for and facilitating patient access to innovative technology and developing and disseminating materials for use by patients, providers, and facilities. Finally, life sciences companies can promote research equity in the industry. For example, life sciences companies can engage and partner with other caregivers and groups to bridge the gap, and promote the need for and involvement in studies and research to include more diversity among investigators. At B. Braun, we are working to ensure the industry is doing its part to mitigate the adverse impacts of health disparities among people and specifically communities of color.

Governance

Finally, governance is foundational to the "E" and "S" of ESG and foundational to a company's overall long-term success and shareholder value. *Governance is about having the right leadership, compliance framework, culture and controls to reduce enterprise risk, drive financial performance and most importantly, keep our patients, providers, people and the planet safe.*

CAN YOU TALK A LITTLE BIT MORE ABOUT WHAT IS HEALTH EQUITY, AND WHY IS IT IMPORTANT?

Health equity is about recognizing and changing the fact that health inequities or differences exist in access to care, actual care and health outcomes – negatively impacting people of color and other marginalized groups. These health differences are avoidable and unjust.

I believe that advancing health equity is both a moral and business imperative. Every organization, across every industry, has a role to play in making health more equitable—within their organizations, in the communities they serve, and across ecosystems. All stakeholders in the healthcare ecosystem have a role to play.

YOU HAVE BEEN INSTRUMENTAL IN DRIVING HEALTH EQUITY PROGRAMS AT B. BRAUN. WHAT ARE SOME EARLY INITIATIVES AND SUCCESSSES IN THIS EFFORT?

In the area of vascular access, one pain point we are solving is IV success rates and outcomes in darker skinned patients. Patients with darker skin have a higher probability of having multiple attempts of catheter insertion which can lead to problems if not addressed. In a study of over 100,000 emergency department patients at Massachusetts General Hospital and Brigham and Women's Hospital, the rate of difficult intravenous access was 58% higher for Black patients. A higher percentage of Black patients are having treatment delays that can lead to infection and longer hospital stays.

To address this pain point, we partnered with health systems and providers like FirstHealth of the Carolinas to deploy the Peripheral Advantage program a year ago, and they reported significant improvements in patient outcomes. Peripheral intravenous catheter, or PIVC, dwell times more than doubled, first stick success increased from 70% to 83.7%, staff PIVC knowledge increased by 21.6%, and patient satisfaction improved by 29%. We are working with the Association for Vascular Access, or AVA, to raise awareness of the issue, get real world evidence on the pervasiveness of the problem and we are working with them and other organizations to raise the standard of care for PIVC access. The bottom line is that darker skinned patients should not have to suffer or risk bad outcomes when technology is available to significantly improve first stick success.

Another important obstacle is the need for more data on specific health inequities. It makes it difficult to track success without baseline data and outcome data.

CAN YOU SHARE SOME OF THE STRUGGLES OR OBSTACLES THAT YOU HAVE FACED IN PROMOTING HEALTH EQUITY AND HOW YOU HAVE OVERCOME THEM?

A primary obstacle to achievements in health equity is the need for a more diverse workforce. I struggle with being the only or one of few people of color and women at the decision table.

I share that with you because when I came there was not a whole lot of action on health equity – not because we did not think it was a business and moral imperative, but rather because often, in order to see and empathize with the inequities, you must have diverse talent in the room where decisions on healthcare solutions and services are being made. To overcome this, I have been focusing on using my platform to evangelize health equity and collaborate with our Chief Medical Officer and Head of Government Affairs who have been great partners in developing a strategy and executing on the strategy.

Another important obstacle is the need for more data on specific health inequities. It makes it difficult to track success without baseline data and outcome data. We can overcome the lack of data by collaborating with partners to do clinical research, such as vascular access partners for our IV access initiative.

HOW DO YOU STAY UP TO DATE ON THE LATEST TRENDS IN SUSTAINABILITY AND ESG?

ESG is such a broad and nebulous topic where the regulatory and stakeholder landscape is constantly evolving. It is imperative to first understand what part of the ESG landscape is relevant to your company and industry and then to stay ahead of the curve. Some tips are listen to MSCI's ESG Now podcasts, read industry ESG public reports and rely on outside counsel and experts.

III. S: Social

As mentioned in Section II.A. (“What Do We Mean By ‘ESG?’”), many ESG concerns central to the life sciences sector generally fall under the “S” category of ESG. Under the principles of bioethics, Autonomy relates to personal agency, or recognizing that the participant or patient always has the right to decide choices affecting them. Beneficence relates to the actor having the well-being of others in mind. Nonmaleficence is an intention to avoid harming or injuring others, an extension of the ethical standards detailed in the Hippocratic Oath. The last of the four principles, Justice, describes fair and equitable treatment across all participants or patients: balancing the benefits with the risks. Some key social issues in the life sciences sector are human capital management, diversity and inclusion in clinical trials, affordable access and pricing, drug safety and safety in clinical trials, business and human rights, animal testing and social impact projects pursued by life sciences companies.

A. Human Capital Management

I. THE IMPORTANCE OF HUMAN CAPITAL MANAGEMENT

Holly Lake, Bianca LaCaille and Brooke Goodlett

Employees are a company’s heart, mind, and hands. All employers need a thorough understanding of employment-related legal issues to ensure compliance with the law and to attract and retain a vibrant, effective workforce. The life sciences sector’s employment-related needs can be uniquely complicated by the ubiquity of trade secrets and proprietary information, strict regulation, an environment that rewards rapid movement, and a history of racial and gender imbalance. Thus, although many of the sector’s legal needs in this area are similar in kind to those in other sectors, life sciences companies often face novel challenges, closer scrutiny, and potentially higher risk.

There has been a lot of discussion about “The Great Resignation” or “The Big Quit” and shorter tenures by new employees, what’s driving it and whether these trends will continue. Certainly, the events of 2020 to today, in addition to the introduction of a new

generation into the workforce, have caused many employees to reevaluate their personal and professional lives and their hierarchy of priorities around work. What does this mean to companies in the life sciences sector? You are likely juggling three pressing needs: hiring to replace talent that has left, retaining current talent, and hiring new talent to support business growth. Not having the right talent in sufficient quantities to get the work done leads to burnout and puts strain on the entire organization. Acknowledging this problem, here are a few tips for navigating the Great Resignation:

- **Value the Data:** Be curious about who is resigning and why. Consider demographics as well – age, gender, race, ethnicity, and tenure are all metrics to evaluate. In looking at the data, specifically look for any patterns or trends and how they can be addressed.

- **Don't Overlook Those Who Stay:** When someone resigns that often means everyone else will have to pick-up the additional workload until a replacement is hired. Being mindful of the health and wellbeing of your workforce and taking steps to prevent burnout and prioritize mental health will be crucial.
- **Support Those Who Decide to Leave:** Often, when an employee gives notice, the reaction is akin to an emotional breakup. Think carefully about what this behavior conveys. The better alternative is to approach these transitions with grace and gratitude. The talent pool is small and careers are long—it is usually best not to burn bridges with a departing employee.

II. LABOR PRACTICES AND CONDITIONS

Holly Lake and Bianca LaCaille

The ESG framework places strong emphasis on a company's environmental and human rights impacts on the communities and people that sustain its operations. Many life sciences companies depend on workers in jurisdictions around the world, and their global workforces are core ESG stakeholders. Investors and regulators (and plaintiffs' counsel) are increasingly scrutinizing businesses' ability to provide for the basic safety, health, and wellbeing of workers. This means, at a minimum, compliance with local labor laws wherever employees work. In the ESG context, it also means compliance with international soft-law norms like standards promulgated by the International Labour Organization, including emphasis on parental leave, support for older workers and social insurance schemes, and minimum and maximum hour guarantees to promote individual time sovereignty. Companies seeking to establish good ESG practices in these areas should conduct jurisdiction-specific impact assessments of their leave and other social support policies, including a comprehensive gap analysis, and integrate findings into their operations, strategic decision making, and supply chains.

In addition to an array of other factors in the last decade, COVID-19 and the role of essential workers in the pandemic turned public attention to workplace conditions and their impact on the physical and mental well-being of the people at the heart of our economy. Companies considering whether and how to transition back to in-person work settings should implement sound policies for a safe and healthy working environment, balancing vaccine mandates or encouragements with federal, state and/or local laws allowing exemptions.

III. WORKFORCE DIVERSITY, EQUITY, AND INCLUSION

Holly Lake and Bianca LaCaille

In many ways, the life sciences sector is top of mind when it comes to diversity, equity, and inclusion in the workplace, with most prominent sector companies being highly vocal about their expansive commitment to increasing representation of women, people of color, LGBTQ+, and people with disabilities, in their workforces. This stated commitment has been generally well received, by stakeholders and investors alike, as the benefits of a diverse and inclusive workplace are well understood. Life sciences companies, however, have continued to struggle in diversifying their workplaces, with the sector continuing to be overwhelmingly White and male. This disconnect between messaging and results has led to highly public criticism by employees, former employees, stakeholders, and media. This public criticism, in turn, has encouraged a torrent of threatened and actual litigation, as well as increased the risk of legal liability and negative press for sector companies. Ensuring diversity, equity, and inclusion at all levels—particularly in leadership roles—of sector companies and creating a culture free of discrimination and exclusion based on race, gender, gender identity, disability and other protected classes are paramount to mitigating these risks. To these ends, life sciences companies should craft and implement thoughtful, expansive policies at all levels, from recruiting and hiring initiatives that result in increased diversity to workplace policies that encourage nurturing and promoting traditionally disadvantaged groups within their organizations.

IV. ENGAGEMENT, CULTURE AND PROFESSIONAL DEVELOPMENT

Holly Lake and Bianca LaCaille

With COVID-19, the Great Resignation, and increased focus on environmental and social rights in the workplace, life sciences companies should prioritize employee workload and project management to better retain talent. Employees who are looking to grow within an organization still exist but are more aware than ever of the impact of reduced teams. Flexible work options, including relaxed location and work hour requirements, open door policies to hear employee concerns and ideas, and professional and mental health counseling services can go a long way in fostering an inclusive work environment where employees feel they can thrive. Companies should also assess whether there is room for increased or flexible leave policies.

V. HUMAN CAPITAL DISCLOSURE RULEMAKING AND TRENDS

Holly Lake, Brooke Goodlett and Bianca LaCaille

Public company boards have long overseen key decisions related to human resources. In recent years, many public company boards have expanded their oversight as investors and other stakeholders have demanded more holistic disclosure and greater board involvement with human capital management. As the COVID-19 pandemic has highlighted, the nature of work is rapidly evolving, and talent and culture are proving to be key assets. In connection with the SEC's modernization of its corporate disclosure requirements in recent years, industry groups and activist investors suggested hundreds of additional human capital data points that the SEC should require issuers to disclose. In 2020, the SEC revised its rule on human capital disclosure under Regulation S-K. The SEC held fast to its belief in a "principles-based" approach that only requires public companies to provide "a description of the registrant's human capital resources...to the extent such disclosures would be material to an understanding of the registrant's business."

This new standard theoretically calls for the disclosure of more information than simply employee headcount, but in practice provides little guidance as to what that information should be. The new rule also declines to define "human capital" because the term may evolve over time and may be defined by different companies in ways that are industry specific. Consequently, these disclosures, as well as the accompanying metrics and measures, will vary and are likely to evolve over time as practice, managerial activities and business environments change.

Notwithstanding the variance of disclosure, while companies have broad discretion in deciding which human capital measures to disclose, some trends have started to emerge:

- **Commitments to Diversity and Inclusion:** Companies are increasingly highlighting commitments and efforts to enhance diversity and inclusion. Key themes include initiatives to empower traditionally disadvantaged groups and bring them into leadership positions, employee participation in affinity groups, diversity statistics and recruitment goals, collaborations with organizations focused on diversity

matters, diversity and inclusion trainings, and third-party diversity and inclusion awards and recognition.

- **Health and Wellness:** In addition to employee incentives and benefits, some companies are prioritizing other health and wellness areas of focus, including their response to the COVID-19 pandemic and employee safety measures. Companies are taking the opportunity to differentiate themselves and discuss how they are embracing new ways of working, such as offering hybrid workplace opportunities or mental health counseling.
- **Culture Values and Surveys:** Some companies are disclosing their cultural values, including disclosing the results of employee engagement surveys, benchmarking reports (which cover a variety of topics such as inclusion, pay and benefits, and learning and development), employee Q&A sessions, unconscious bias trainings, leadership team events, and onboarding and exit surveys.
- **Employee Development and Training Programs:** Many companies have formal mentorship, training, and development programs and are taking the opportunity to discuss the value of these programs in greater detail.
- **Employee Incentives and Benefits:** Some companies are also choosing to highlight the incentives and benefits they offer employees, which can be a key tool for retention and recruitment (eg, insurance packages, stock-based compensation awards, and cash-based performance bonus awards).
- **Employee Turnover and Tenure Information:** While a less common measurement to include, employee turnover and tenure is a metric that stakeholders will likely be increasingly interested in seeing.
- **Number and Type of Employees, Geographical Distribution Gender, Race and Ethnicity:** Lastly, some companies provide quantitative metrics, including not only the number of employees, but their numerical distribution in certain key categories (eg, full time, part-time, seasonal, contractors, job title (eg, engineering, sales and marketing, research, general and administrative, business development), geographic distribution, gender and race and ethnicity).

It is clear that human capital has rapidly emerged as a critical focus area for stakeholders. It is also clear that

human capital disclosures are highly individualized and industry dependent. As time passes, we will likely see more uniformity in the types of metrics and measurements being disclosed, especially in light of human capital's inclusion on the SEC's short-term rulemaking agenda. In the meantime, this can serve as a helpful guide in thinking through the types of disclosures public companies are considering. Companies should continue to think critically to ensure its disclosure is consistent and comparable across its peer group.

VI. DEFINING DIVERSITY

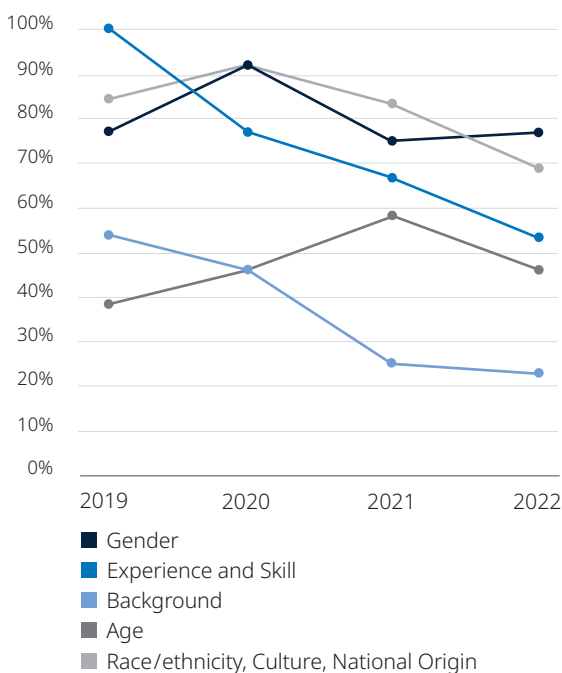
Brooke Goodlett and DLA Piper ESG Data Analytics

What does a "diverse" workforce mean? From 2019 to 2022, we analyzed discussions of workplace and Board diversity by fifteen life sciences companies to quantify which diversity categories were highlighted annually by these companies. While gender, race/ethnicity, age and experience/skill were consistently mentioned, some companies also highlighted diversity in disability, LGBTQ+ status, perspectives, international experience veteran status, geography, tenure and religion.

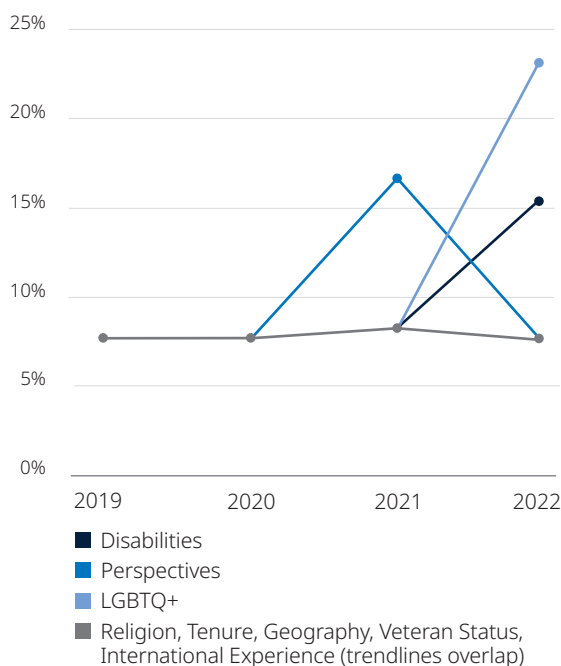
- **Gender** had the highest incidence by 2022 but started as the second highest incidence (behind "background") in 2019 at 77% in both 2019 and 2020. Its incidence peaked in 2022 with 92% of companies highlighting gender diversity.

- **Race and Ethnicity**, including culture and national origin, peaked in 2020 and 2021, at 92% and 83% respectively. This trend likely reflects the increased importance placed by companies on racial justice following the 2020 George Floyd protests.
- **Age** was highlighted in 38% of companies in 2019, 58% in 2021 and 46% in 2022, with a net result of a slight increase of incidence.
- **Experience, Skill and Background** diversity significantly decreased in incidence. While experience/skill decreased from 100% in 2019 to 54% by 2022, background decreased from 54% to 23% in the same time frame. Both terms' usage were roughly cut in half in four years. This trend likely reflects the greater importance placed on gender, race and ethnicity and other forms of diversity over the four-year period studied.
- Other terms that were used occasionally included disability, LGBTQ+ status, perspectives, international experience, veteran status, geography, tenure and religion. Each of these were used at 8% every year, with increases in discussions of diversity in disability, LGBTQ+ status and perspectives in subsequent years. The usage of disability was at 15% and LGBTQ+ status at 23% in 2022. The usage of perspectives peaked at 17% in 2021.

Diversity Definitions Prevalence 2019-2022



Diversity Definitions Prevalence 2019-2022



B. Health Equity

Brooke Goodlett and Joanna Kass

Health equity has become a recent area of focus for the life sciences sector, in response to the COVID-19 pandemic which highlighted global health disparities. The pandemic revealed the longstanding systemic barriers to health in low-income countries that struggled to obtain a consistent supply of medicines and vaccines. According to the Center for Disease Control (CDC), health equity is an equal opportunity for people to attain the highest level of health and well-being. The CDC has integrated health equity as a foundational value through its CORE strategy, which aims to cultivate comprehensive health equity, optimize interventions, reinforce and expand robust partnerships, and enhance capacity and workplace diversity, inclusion, and engagement.

Many life sciences companies have followed the CDC by implementing similar health equity strategies. For instance, one Fortune 100 pharmaceutical company implemented an initiative in May 2022 to provide access to its patented and off-patent medicines and vaccines on a not-for-profit basis to 45 low-income countries. This initiative has enabled collaboration with the Ministries of Health in several African nations to improve healthcare education and optimize supply chains.

Telehealth, or the delivery of healthcare services via telecommunications technology, has also emerged as a potential solution to mitigate health inequities. Telehealth eliminates transportation barriers, as well as the cost of lost wages, that minority populations might experience by having to physically travel to an appointment. However, it will be important to ensure that the digital divide does not have the potential to further increase health inequality among populations without access to technology.

Ultimately, health equity has a broad focus on delivering unbiased treatment and overcoming structural determinants that restrict people's access to healthcare. Life sciences companies that make health equity a business priority will likely enhance their reputation in the market and benefit by improving universal access to their products.

C. Diversity and Inclusion in Clinical Trials

Raymond Williams and Kirsten Axelsen

Despite considerable effort from the private and public sector to achieve more adequate rates of clinical trial enrollment, there is still significant underrepresentation of certain races and ethnicities in late-stage clinical development for drugs approved in the US. When clinical

When clinical trials for new drug approvals fail to adequately represent racial and ethnic groups, there is a lost opportunity to provide meaningful insight for people who will be ultimately be prescribed these medications.

trials for new drug approvals fail to adequately represent racial and ethnic groups, there is a lost opportunity to provide meaningful insight for people who will be ultimately be prescribed these medications. This underrepresentation undermines a source of healthcare that may be particularly useful for people who are currently underrepresented in existing therapies.

The Food and Drug Administration's (FDA) Drug Trials Snapshot examines race, ethnicity, age and gender of global clinical trial participants for drugs approved in a given year. In 2020, for the 53 drugs approved, 75% of the participants were White, 8% Black, 11% Hispanic and 6% Asian, women were 56% and people aged 65 or older were 30%. In comparison, based on the 2019 US Census, Blacks were 13% of the population, Hispanics 19%, Asians 6%, women 51% and people aged 65 or over 16.5%. Blacks and Hispanics continue to be underrepresented, while women, Asians and people over 65 are more adequately reflected relative to the US population.

In November 2020, the FDA issued guidance providing recommendations on how clinical trial sponsors can approach enrollment of underrepresented patient populations. This effort builds on more than a decade of initiatives to increase racial and ethnic diversity in clinical

trials at the FDA and National Institutes of Health. Many of the FDA stated goals are centered around further dialogue and communication with sponsors, patients and other community-level stakeholders. The agency recommended changing criteria to include participants in studies that historically have disproportionately excluded people from underrepresented groups.

As of April 2022, the FDA issued a news release with updated guidance for developing plans to enroll more participants from underrepresented racial and ethnic groups in the US into clinical trials. The draft guidance recommends that sponsors of medical products develop and submit a Race and Ethnicity Diversity Plan (Plan) to the FDA early in clinical development, in accordance with certain timelines depending on the type of product. Sponsors should define enrollment goals and the proposed assessment for underrepresented groups in their plan.

While there have been innovations in clinical trial implementation, including remote monitoring and digitally enabled trials that may facilitate enrollment, this may not be sufficient to achieve adequate representation in late-stage trials. The issue goes beyond communication and trust, but also includes managing co-morbid conditions more prevalent in certain races and ethnicities and differences in the expected efficacy of treatment in some under-represented populations. Sponsors and doctors can do their part to diversify clinical trial research by incorporating new approaches, including outreach and education programs, to help bring better awareness of clinical trials to all communities.

D. Affordable Access and Pricing

Raymond Williams, Jim Greenwood and Kirsten Axelsen

The response of America's biopharmaceutical industry in rapidly developing vaccines and antivirals to combat COVID-19 has highlighted our nation's leading role in innovating remarkable new medicines. AIDS is now a chronic disease rather than a death sentence. Statins have reduced the rate of death from heart attack by 25%. Immunotherapies are saving the lives of cancer patients without the ordeal of previous chemotherapy. New innovations in gene and cell therapy promise to cure diseases caused by genetic abnormalities.

Unfortunately, these treatments and cures are not equitably available to everyone. The uninsured and those with insurance plans that require significant out-of-

pocket expenditures too often find themselves either unable to afford their medicines or bear unreasonable costs to fill their prescriptions.

State and federal policy makers, understandably, have responded to this challenge by attempting to reduce cost to patients and to government healthcare programs by imposing price controls on prescription drugs. Arguably, though, focusing on prices doesn't solve the problem. While the consumer price index increased 6.8% in 2021, net prices of prescription drugs fell 0.3%. A far better approach would focus on patient out-of-pocket costs. Insurance deductibles were designed to give patients "skin in the game" so they would be incentivized to engage in more cost-conscious healthcare consumption. This may make sense when patients consider whether to call an ambulance or to go to an emergency room. But when patients are prescribed medicines, they don't really have much of a choice. When they can't afford to pay high deductibles, they get sicker and may need costly hospital care.

While the consumer price index increased 6.8% in 2021, net prices of prescription drugs fell 0.3%.

In 2022 the Inflation Reduction Act (IRA) was passed into law. This legislation will cap prescription drug costs for seniors and disabled people enrolled in Medicare prescription drug programs and allow them to pay costs monthly rather than all up front. It will also eliminate co-pays for certain adult vaccines and limit co-pays for insulins. The IRA will increase federal subsidies to a group of lower income people in Medicare Part D who make less than 150% of the federal poverty level. The IRA will also allow the federal government to set the prices of the largest selling medicines in Medicare that have been on the market for 9 to 13 years. The price setting will result in significant reductions in prices and revenues as the federal government is charged with reducing prices to levels well below those already achieved through private market negotiation in Medicare. Furthermore, the IRA will require biopharma manufacturers to pay the federal government back for price increases in excess of consumer inflation which is expected to reduce price increases on a list basis.

This focus on drug prices in Medicare is unlikely to solve the problem of prescription drug affordability. While the

consumer price index increases 6.8% in 2021, net prices of prescription drugs fell 0.3% so considering discounts drug price growth was largely controlled by private and public market mechanisms. While price controls on medicines have popular and bi-partisan support they have consequences on the private market within and beyond Medicare. This law is expected to reduce investment in post market study, skew investment toward medicines that are out of scope of the policy or have price controls later in the lifecycle, discourage generic and biosimilar competition, and raise drug prices at launch.

E. Drug Safety and Safety in Clinical Trials

Katie Insogna and Matthew Holian

Safety is mission-critical to the pharmaceutical sector, particularly safety of drugs and safety of clinical trial participants.

Drug Safety. Federal regulations require pharmaceutical companies to identify safety risks with the use of their prescription or over-the-counter medications in each medication's label, which includes prescribing information for physicians, patient information, and carton labeling. 21 CFR § 201.57 (prescription medications); § 201.66 (over-the-counter medications). Manufacturers likewise are required to update the label when they become aware of newly acquired information about the safety or efficacy of the medication. 21 CFR § 201.56(a)(2). Certain changes to the label require pre-approval from FDA; other changes may be made unilaterally by manufacturers. 21 CFR § 314.70. All information in the label, including warnings of risks of the medication, must be supported by substantial evidence. 21 CFR § 201.56(a)(3).

Safety in Clinical Trials. Federal regulations require pharmaceutical companies to warn clinical trial participants of known risks of use of the medication(s) administered in the trial. To satisfy this requirement, participants must sign an informed consent form that identifies the known risks in advance of their participation. 21 CFR § 50.20. Manufacturers also must obtain the approval of an independent oversight committee, called an institutional review board or "IRB," before conducting a clinical trial. 21 CFR § 56.03. Finally, manufacturers must warn the investigators conducting the trial of the risks of the medication(s), which they do

through an investigator's brochure. 21 CFR § 312.55(a). The brochure must be updated as new information about the safety and efficacy of the medication(s) becomes known to the manufacturer. 21 CFR § 312.55(b).

F. Business and Human Rights

Sonakshi Kapoor

Life sciences businesses are increasingly integrating a human rights-based approach in their products and operations to identify and manage adverse human rights impacts, and to respond to scrutiny from investors, consumers, governments, and civil society. Today more than ever, life sciences companies face legal, financial, operational, and reputational risks associated with their human rights impacts. The landscape of transnational business and human rights legal risk is changing rapidly in jurisdictions around the world, including the US, Australia, Canada, England, and The Netherlands. Robust action will soon be essential to meeting regulatory requirements worldwide and ensuring a competitive advantage.

Life sciences businesses in the US looking to develop effective human rights compliance programs should consider whether the UN Guiding Principles on Business and Human Rights (UNGPs) would serve as an effective tool. The UNGPs are the leading international framework for businesses to identify and manage actual and potential human rights risks. They provide, among other things, guidance for companies to identify adverse human rights impacts and create policies and compliance procedures to address and integrate key findings. This also involves consultations with potentially affected groups and other relevant stakeholders. Common human rights impacts in the life sciences sector cover access to medicines and healthcare services, patient safety, unethical or exploitative conduct in clinical research and trials, labor exploitation, and the use of forced and child labor in supply chains.

Human rights due diligence (HRDD) is another crucial component. Robust HRDD allows life sciences businesses to integrate key findings from the risk assessments across relevant internal functions and processes. HRDD is also relevant to corporate transactions, such as mergers and acquisitions. The HRDD process finds support in the UNGPs, the GRI standards, and proposal for mandatory HRDD in the European Union focused on identifying, mitigating, and reporting adverse human rights impacts. The HRDD process is now moving from the folds of soft law standards to binding regulations.



The ethical complications of animal testing create a challenge in formulating relevant ESG strategies

G. Animal Testing

Brooke Goodlett and Omkar Mahajan

Animal testing, animal experimentation, or animal research refers to the use of non-human animals as test subjects in controlled experiments. The studies derived from such experiments collect information on behavioral or biological changes in the animal, and the results ultimately have applications in a range of industries and activities. Specifically, for the scientific community, animal models are a significant part of the research process, as these allow researchers to observe a living organism's range of reactions to specific biological and chemical factors. The ethical complications of animal testing create a challenge in formulating relevant ESG strategies, as numerous ethical nuances can translate into distinct screening approaches. An increasing number of life sciences companies, particularly those in the bioengineering space, have heavily invested in alternative methods to animal testing, such as the use of computer models using artificial intelligence and machine learning analysis and the use of microfluidic chips (also known as "organs on a chip").

ISS ESG's Animal Testing screen evaluated more than 2,000 companies (as of July 2021) and separates the companies' involvement in two groups: Pharmaceutical and Non-Pharmaceutical. Out of the 2,000 companies involved in animal testing, 65% were targeted for pharmaceutical involvement, 28% for non-

pharmaceutical involvement, while 7% overlapped with both groups. It is worth noting that pharmaceutical companies at times cannot opt out of animal testing due to regional requirements, because a country's legislation often mandates animal experiments for new medical products and services before human clinical trials can be conducted. Previously, in the US, the FDA requires animal testing on many drugs and devices in pre-clinical trials for safety and efficacy purposes. However, in December 2022, President Joe Biden signed the FDA Modernization Act 2.0, which ended the 1938 federal mandate that drugs and devices had to be tested on animals in pre-clinical trials before being used in human trials. Although this recent legislation doesn't outright ban animal testing, it allows pharmaceutical companies to use alternative means to animal testing, such as microfluidic chips.

Simply put, regional differences in animal testing methods, uses, and regulations (or lack thereof) make it difficult to gauge company involvement. For example, cruelty-free brands commit to making products with no animal testing at any point throughout the process, yet the term "cruelty-free" is unregulated, meaning any product can use this label without repercussion, whether they are cruelty-free or not. Nonetheless, a set of principles have been established to serve as

a framework for a more humane use of animal testing in research. The guiding principles are defined as 3Rs: “Replacement, Reduction, and Refinement” to encourage the use of non-animal based models when possible, to reduce the number of animals for research, and to improve the well-being of animals where their use may be unavoidable depending on the context. Indeed, recent legislation and company policies on animal testing have been incorporating the 3Rs framework in their ethics guidelines.

H. Social Impact Projects

Brooke Goodlett and UTGLSI

A social impact project is a corporate initiative focused on leveraging a company’s resources to increase their impact or benefit towards communities in need. Corporate social impact projects can be internal corporate initiatives or separate foundations established and supported by a company. Corporate social impact projects tend to relate—but are not limited to—the core functions of the business, and directly impact a new set of stakeholders: communities, peoples, or issues around the globe. Across the life sciences industry, there are a variety of opportunities for companies to provide a positive social impact. For instance, in the pharmaceutical sector, companies often take on initiatives to disseminate drugs to underrepresented communities in need of important medicines. Vaccine manufacturers, as an example, have distributed Covid-19 vaccines for free to underserved communities around the world. Medical device or medtech companies, on the other hand, often go the extra mile to aggregate, publish, and analyze data to help medical professionals deliver treatments faster. From a more generalist approach, life sciences companies also take on environmental initiatives and source part of their up or downstream business operations with entirely renewable energy or net carbon neutrality goals. Social impact projects are inherently diverse in the life sciences industry and are ultimately dependent on the objectives and outlook of a specific corporation.

Improving universal access to healthcare has been a recent area of focus for life sciences companies. For instance, one large American drug distribution company established a Health Zones initiative to increase access to health services in underserved communities. According to this company’s 2021 ESG Report published in 2022, they are focused on addressing health



Social impact projects are inherently diverse in the life sciences industry and are ultimately dependent on the objectives and outlook of a specific corporation.

disparities in the community to mitigate racial inequity. They launched health zones in five states, and these zones enable access to better housing, education, food, and transportation. This company also provides a program with free health screenings, wellness information, and consultations for disadvantaged communities across the nation. The drug distributor aims to provide 4 million free biometric screenings by 2030. These and similar social impact projects can help life sciences companies further their ESG mission and create a positive social impact.

IV. G: Governance

A. ESG Board Oversight

Andrew Ledbetter, Brooke Goodlett and DLA Piper ESG Data Analytics

Investors are increasingly expecting boards of directors to oversee ESG. Some major asset managers have voted against directors, particularly nominating and corporate governance committee chairs, and even entire boards, due to a perceived lack of ESG oversight. Often, companies designate ESG responsibility to the nominating and corporate governance committee (given its role in “governance”), although to a lesser extent companies might task ESG oversight to the audit committee. Even if not specifically tasked with ESG oversight, the audit committee also plays an important function in ESG oversight by overseeing the company’s disclosure controls and procedures and for its general oversight of material risks. Additionally, some publicly traded companies are designating oversight over workforce-level human capital management, such as diversity and inclusion initiatives, to the compensation committee.

Boards can also oversee ESG by including it on meeting agendas and in committee read-outs or providing training and other materials related to ESG to the board.

We expect that dedicated committees may emerge in industries where ESG oversight is particularly important, such as natural resources or energy companies. A 2021 survey by DLA Piper ESG Data Analytics found that over half of Fortune 100 companies have designated a board committee tasked with overseeing ESG initiatives or have expressly delegated ESG initiatives or climate transition oversight to their nominating and corporate governance committee (and, to a lesser extent, audit committee). Our study further found that there was only moderate correlation between board oversight of ESG and high ESG ratings, which suggests that the impact of such overt ESG board oversight is evolving and just one piece of developing a robust ESG strategy.

The specific duties of any board committee regarding ESG would generally be included in the committee’s charter. Boards can also oversee ESG by including it on meeting agendas and in committee read-outs or providing training and other materials related to ESG to the board.

ISS and Glass Lewis have also adopted policy updates in 2022 for the 2023 proxy season requiring board oversight of ESG issues. For companies that are significant GHG emitters through their operations or value chain, identified as those in the Climate Action 100+ Focus Group, ISS will generally recommend “against” or “withhold” votes for the responsible committee chair on a case-by-case basis where ISS determines the company is not taking minimum steps needed to understand, assess and mitigate climate change risks to the company and the larger economy. For companies to which this is applicable, the policy requires both disclosure in accordance with a recognized framework and quantitative GHG reduction targets. ISS will consider, among other factors, relevant market and company factors.

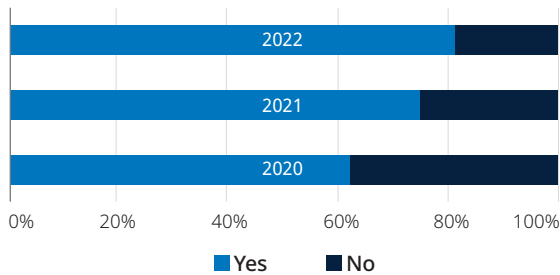
Glass Lewis adopted a nearly identical policy for high emitters for the 2023 proxy season, noting that it expects high emitters like those identified by Climate Action 100+ to provide climate-related disclosures in line with the Taskforce for Climate-Related Financial Disclosures, or TCFD, and that it may recommend votes against responsible directors for not doing so. Additionally, Glass Lewis will generally recommend “against” or “withhold” votes for responsible directors if a company does not provide explicit disclosure about the board’s role in overseeing ESG issues. In addition, both ISS and Glass Lewis have adopted “Say on Climate” policies: ISS will recommend votes on a case-by-case basis on both management and shareholder proposals to approve a climate transition action plan and shareholder proposals requesting a Say on Climate vote or other climate-related actions, based on the completeness and rigor of a company’s climate-related disclosures and its actual GHG emissions performance,

Out of the 16 life sciences companies in our 2020-2022 Dataset, the number of companies that had a dedicated ESG committee increased by 25% from 6% in 2020 to 31% in 2022.

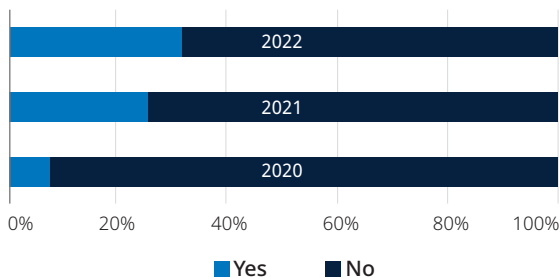
while Glass Lewis will generally oppose shareholder proposals seeking to approve climate transition plans or adopt a Say on Climate vote and will consider management proposals seeking to approve a climate transition plan on a case-by-case basis.

In the life sciences sector, where boards establish a dedicated ESG or CSR committee, that committee is often responsible for overseeing risk and compliance functions such as safety and product quality. DLA Piper ESG Data Analytics found that, out of the 16 life sciences companies in our 2020-2022 Dataset, the number of companies that had a dedicated ESG committee increased by 25% from 6% in 2020 to 31% in 2022. We defined a dedicated ESG committee as a committee overseeing ESG, climate change or CSR that is separate from the audit, compensation or corporate governance committees, even if that committee also oversees other initiatives like risk, compliance, product quality or safety. This 25% increase in companies with a dedicated board committee is on the rise, but is a less common feature of ESG governance than providing additional ESG disclosure.

ESG / CSR Disclosure in Proxy 2020–2022



Dedicated ESG / CSR Committee 2020–2022



B. Building Your Internal, Cross-Functional ESG Team

Andrew Ledbetter, Brooke Goodlett and DLA Piper ESG Data Analytics

I. MANAGEMENT ESG COMMITTEES

More common than a dedicated board committee overseeing ESG is a dedicated cross-functional management committee representing the legal, compliance, internal audit, operations, investor relations, marketing and finance departments and, resources permitting, also including ESG executives and staff. This management committee would generally be responsible for determining the company's ESG priorities and initiatives and ensuring that these priorities and initiatives are supported by the company's business strategy and reported to the board and key stakeholders.

II. CHIEF SUSTAINABILITY OFFICERS AND OTHER EXECUTIVE-LEVEL ESG DIRECTORS

Some companies have a chief sustainability officer that serves as an orchestrator of ESG strategy across all departments. The role of a chief sustainability officer (CSO) is to be a change agent who emphasizes sustainability initiatives across all functional units within the company. Most CSOs are appointed internally from an operational role that liaises with multiple units within the company, often one related to sustainability. The CSO usually works closely with the risk department, the teams responsible for internal controls, the audit committee, and the CFO. While reporting lines for CSOs differ, if it is important enough to have a CSO, organizations usually conclude the CSO should have organizational structure and authority that can drive impactful change within the company. Other common reporting lines for CSOs are to the CFO, General Counsel, or the head of investor relations or marketing. In recent years, however, companies have largely moved sustainability out of their marketing or investor relations functions, and even out of their legal and compliance functions, and into a direct reporting line to the COO, CFO or CEO, where ESG can have a broader impact on corporate strategy and budgeting.

ESG leaders can have various titles, and another common title is ESG director. The main difference between a CSO and an ESG director is that a CSO generally focuses on a wholistic sustainability strategy while ESG directors generally focus on ESG reporting. We expect the role of CSOs and ESG directors to evolve as the regulatory landscape on ESG matters and related stakeholder expectations continues to change.

Of the 40 life sciences companies in our 2021-2022 Dataset, 35% had an ESG director, and this number was consistent from 2021 to 2022. This trend seems to suggest that the life sciences companies that have hired an ESG director see a value in the role, while also likely reflecting that many life sciences companies administer tight budgets and may be waiting for regulatory requirements and market patterns to take shape before engaging specialist executives. For example, among the Fortune 100 companies we surveyed in 2021, 75% had an ESG director, likely reflecting the greater resources that Fortune 100 companies may have to spend on ESG initiatives. We defined an ESG director as a management-level role with a title conveying responsibility for sustainability or ESG matters.

III. ESG STAFF

Companies with robust ESG programs will often designate employees to assist with ESG reporting. ESG staff members are generally tasked with:

- collecting ESG data from various groups inside and outside of the company
- calculating the company's GHG emissions and other key ESG metrics
- completing third-party ESG surveys and reporting to voluntary reporting frameworks like the CDP
- ensuring that the company's disclosures across its ESG reports, press releases, sustainability websites, investor conferences, responses to voluntary reporting frameworks, and SEC filings are accurate, consistent and complete
- preparing annual ESG reports, sustainability websites or proxy disclosures
- identifying key ESG stakeholders, and conducting stakeholder outreach efforts, such as responding to stakeholder requests for information, and engaging stakeholders to determine their ESG priorities

- planning and overseeing ESG investor days to promote stakeholder engagement
- conducting ESG materiality assessment
- planning and overseeing social impact projects
- overseeing and arranging third-party ESG-related audits of the company, such as verifications under ISO Section 26000 or 14001 or racial equity audits and
- overseeing and arranging ESG-related audits of third-party suppliers and others in the company's value chain.

ESG staff can be an important resource for ensuring that a company's ESG program and reporting has effective disclosure controls and procedures and managing legal and reputational risks, such as greenwashing claims. They also can be a key resource to execute on management's ESG priorities.

Of the 40 life sciences companies in our 2021-2022 Dataset, the percentage of life sciences companies that hired additional ESG staff increased slightly from 45% in 2021 to 48% in 2022. As with our ESG director analysis, the rate of companies with ESG staff in our 2021-2022 Dataset is significantly lower than the 75% of Fortune 100 companies we surveyed in 2021, which is not surprising given that Fortune 100 companies generally have more resources to spend on ESG initiatives. The slight increase in companies with dedicated ESG staff in our 2021-2022 Dataset seems to indicate that life sciences companies that have hired ESG staff have determined that these employees bring value to their organization, with some new companies this year hiring new ESG staff.

C. ESG Definition Disclosure Analysis

Brooke Goodlett and DLA Piper ESG Data Analytics

Central to ESG governance is clarifying what the company means by "ESG," and what ESG issues are material to the company. As we describe further in Section II.A. ("What Do We Mean By 'ESG?'"), ESG is an umbrella term representing a wide array of environmental, social and governance concerns, and even within particular life sciences companies, its definition changes widely from year to year. DLA Piper ESG Data Analytics has analyzed how certain life sciences companies have defined ESG, and has presented these findings in a short (year over year) and longer (four-year) timeframe.

I. SHORT-TERM ESG DEFINITION TRENDS: 2021-2022

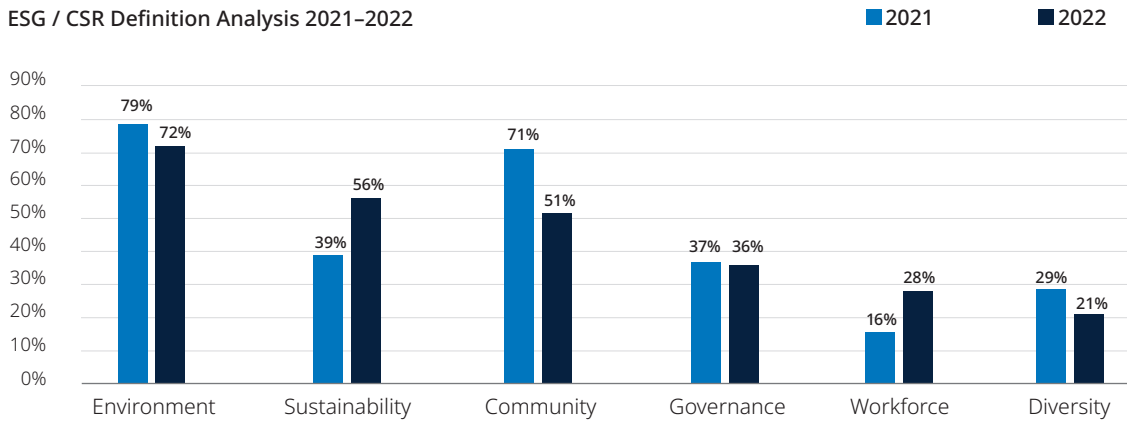
From 2019 to 2022, we analyzed how, if at all, 40 life sciences companies defined ESG or corporate social responsibility (CSR) from year-to-year. 92% of the companies analyzed in 2021 and 2022 defined either “ESG” or “CSR” in some capacity. While usage of the terms “environment,” “climate” or “sustainability” increased, usage of “community” and “diversity” decreased.

These trends demonstrate the shifting notions of what ESG entails. In recent years, concerns related to the environment, including climate transition, climate change, greenhouse gas reduction, waste and water management, and protecting forests and biodiversity, have increasingly dominated the ESG space. While human capital management and social concerns remain important to firms, these issues generally have historically sat under the umbrella of human resources and are increasingly being considered distinct from the company’s ESG efforts. Governance, meanwhile, has historically been considered the domain of boards, and therefore a company’s governance practices generally

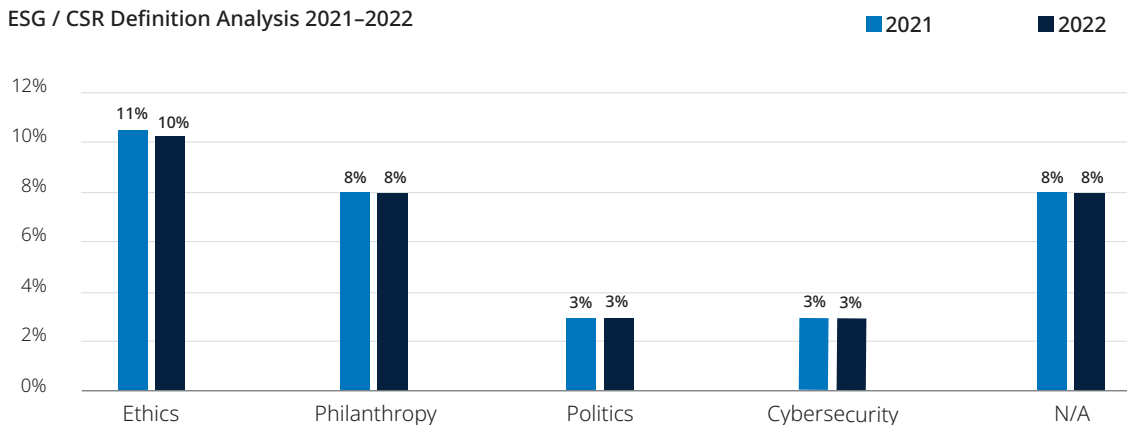
have distinct reporting lines from a company’s overall ESG or sustainability teams.

- “Environment” or “climate” usage increased by 7% year-over-year to 79% by 2022.
- “Sustainability” usage increased by 17% year-over-year to 56% in 2022.
- “Governance” usage remained similar between the years, decreasing just 1% year-over-year to 36% in 2022.
- Usage of words referencing employees, such as “health,” “talent,” “our people” and “workforce,” increased by 8% year-over-year to 28% in 2022, while “diversity,” “diversity and inclusion,” or “diversity, equity and inclusion” usage decreased 8% year-over-year to 21% by 2022.
- Usage of “community” “social” and “native people” or similar or a synonym to it decreased by 15% year-over-year to 51% by 2022.

ESG / CSR Definition Analysis 2021–2022



ESG / CSR Definition Analysis 2021–2022



II. FOUR-YEAR ESG DEFINITION TRENDS: 2019-2022

Another trend emerges when analyzing ESG or CSR definitions year-over-year for a longer period of time: the definition of ESG sways with market trends. From 2019 to 2022, we analyzed how, if at all, fifteen life sciences companies defined ESG or CSR from year to year. In 2019, half of the life sciences companies analyzed did not define ESG or CSR, at all, but by 2022, all did. This trend demonstrates how companies have ramped up ESG governance in the last four years. The most commonly used terms were:

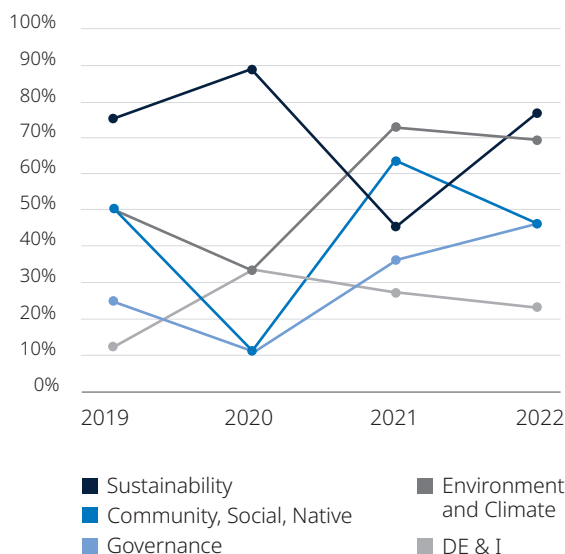
- sustainability
- environment/climate
- community
- diversity
- governance and
- workforce

Other less frequently used words included politics, philanthropy, cybersecurity and ethics. While the less frequently used terms decreased in usage from 2019 to 2022, the frequently used terms increased in usage.

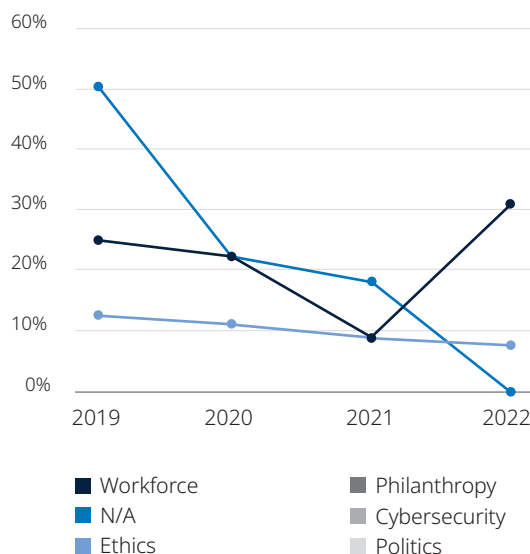
- “Sustainability” usage started at 75% of companies analyzed in 2019, peaked at 89% in 2020 and ended at 77% by 2022 for a net effect of increasing slightly in usage by 2%.
- “Environment” or “climate” usage started at 50% of companies analyzed in 2019, peaked at 73% in 2021 and ended at 69% in 2022 with a net effect of increasing 19% in usage.

- “Community” “social” and “native people” usage started at 50% of companies analyzed in 2019, peaked at 64% in 2021 and ended at 46% usage by 2022, for a net effect of decreasing slightly in usage by 4%.
- “Diversity,” “diversity and inclusion,” or “diversity, equity and inclusion” usage started at 13% of companies analyzed in 2019, peaked at 33% usage in 2020 and ended with 23% usage in 2022 for a net effect of increasing 10%. The spike in “diversity” usage in 2020 is likely explained by the increased importance placed by companies on racial justice following the 2020 George Floyd protests and demonstrates that this attention did not maintain this momentum in recent years.
- “Governance” usage started at 25% of companies analyzed in 2019, dropped to 11% in 2020 and increased every year after to end at 46% in 2022. Overall, it increased 21%.
- “Workforce” usage started at 25% of companies analyzed in 2019, decreased to 9% by 2021 but increased 31% by 2022 for an overall slight increase by 6%. The major bump of “workforce” usage in 2022 is likely explained by increased attention to human capital management in the midst of “the Great Resignation.”
- Each of politics, philanthropy, cybersecurity and ethics had the same pattern of usage. Measured independently, each term was used by 13% of companies analyzed in 2019 and continually dropped in usage to 8% by 2022.

ESG / CSR Definitions 2019–2022



ESG / CSR Definitions 2019–2022



D. Voluntary ESG Disclosures

Sanjay Shirodkar, Brooke Goodlett and DLA Piper ESG Data Analytics

I. BASICS OF ESG REPORTING

An increasing number of companies are providing voluntary ESG disclosures to investors and other stakeholders, typically in the form of an ESG report, ESG or sustainability website, a stand-alone ESG update in the company's proxy statement and, to a lesser extent, in annual and quarterly reports filed with the SEC.

An ESG report, also called a sustainability report or CSR report, is a voluntary report describing the company's ESG priorities, programs, metrics and progress. ESG reports typically include such information as greenhouse gas emissions reporting, information about a company's human capital management and diversity and inclusion programs, information about the company's ongoing social impact projects, and other information about a company's ESG initiatives. More complex ESG reports utilize one or more ESG reporting frameworks, which are discussed in more detail in Section IV.E ("ESG Reporting Frameworks and Ratings"). Companies with mature ESG programs might also produce separate ESG reports on discrete ESG topics, such as a report on access to medicine, climate justice or diversity and inclusion, that are targeted towards certain topics or stakeholders.

As investors continue to engage with companies on ESG, we have seen a rise in high-level disclosures related to ESG in annual proxy statements. Among the 16 life sciences companies surveyed in our 2020-2022 Dataset, the number of companies including ESG information in their proxy statements increased steadily from 63% in 2020 to 75% in 2021 and 81% in 2022.

ESG priorities, as well as standards, norms and approaches to these priorities, vary greatly from sector to sector, and even with respect to companies in the same sector. For this reason, the creation of a "one size fits all" disclosure regime will likely not be feasible, and companies preparing voluntary ESG disclosures should demonstrate how their management teams actually evaluate and address ESG issues. Companies preparing voluntary ESG disclosures should consider the following guidelines:

- **Tell the company's ESG story, with a focus on key ESG risks and stakeholder concerns.** The purpose of an ESG disclosure is to tell the company's "ESG story" – to explain how sustainability aligns with the company's mission and how the company manages ESG risks and leverages ESG opportunities. As discussed in Section II.A ("What Do We Mean By 'ESG?'"), ESG is an umbrella term accompanying a wide variety of topics, and it can be difficult for a company to determine which topics are material to the company. SASB's "Materiality Map"™ and other reporting standards are a helpful place to start to identify the ESG topics a company's investors and other stakeholders are interested in and relevant data related to those topics. However, overreliance on reporting frameworks and ESG ratings can distract a company from its core mission and values, and from the priorities of its investors and key stakeholders. It is therefore important that the company's ESG mission is tailored to the company. For life sciences companies, social or "S" issues like the principles of bioethics, human capital management, product safety and access, governance or "G" issues like ESG governance and management, and environmental or "E" issues like managing climate risks and climate transition, are common key ESG priorities.
- **Understand the audience and purpose.** Consider which, if any, significant investors or other key stakeholders have expressed an interest in the company's management of ESG risks and disclosure of ESG data, and formulate a response tailored to the material concerns of these stakeholders and, in particular, investors. If this issue has not yet been raised by any major investors or other stakeholders, it would still be wise to proactively manage and disclose ESG risks and data- as noted in Section II.C ("Why Is ESG Important? Activism, Shareholder Proposals and Governance Engagement"), waiting until investors or other key stakeholders demand ESG data puts the company on its "back foot" when formulating a response. Additionally, the new CSRD and proposed SEC climate rules may make certain ESG disclosures mandatory in the near term, including for some private US companies, in the case of the CSRD.

- **Avoid approaching ESG as a check-the-box exercise; US regulators are paying attention.** Overreliance on reporting frameworks and ESG ratings can distract a company from its core mission and values, and from the priorities of its investors and key stakeholders. As discussed in Section IV.F (“ESG Materiality and Tools for Navigating Differing Stakeholder Concerns”), life sciences companies can conduct shareholder engagement, materiality assessments and competitive studies and peer group analyses to formulate thoughtful ESG initiatives. It is also important to consider SEC comment letters in determining the ESG disclosure and how much data and information is included in a SEC filing. The SEC has been reviewing SEC filings and asking some difficult questions surrounding issues such as materiality, direct and indirect consequences of climate related regulation or business trends, and pending climate change related legislation, regulation and international accords.
- **Use verified data and avoid greenwashing or puffery.** As we discuss in further detail in Section VII (“ESG Risks”), companies have been sued or are facing regulatory enforcement actions for “cherry picking” ESG data or making broad statements about their ESG practices that are not grounded in reality, a practice commonly known as “greenwashing.”

Risks related to “washing” are not limited to the environmental sphere. Companies that have made statements in SEC filings that they value diversity have faced shareholder derivative actions alleging that the companies committed federal securities law violations by proclaiming a commitment to diversity while maintaining non-diverse boards. Some companies have been accused of “rainbow-washing” – using rainbow logo colors or statements touting the company’s support of the LGBTQ+ community during pride month, while facing discrimination claims by LGBTQ+ employees.

To avoid “greenwashing,” “rainbow-washing,” or similar accusations, it is important that companies avoid vague statements or words with no clear meaning (like “eco-friendly”), avoid “puffery” or stretching the company’s achievements, and rely on measurable data that is verified by effective disclosure controls and procedures. For example, in the environmental sphere, resources permitting, a company can utilize developed frameworks like TCFD to report GHG emissions and the Science Based Targets initiative, or SBTi’s, methodologies and

practices to set and measure emissions reductions and net zero targets. In the social sphere, a best-in-class diversity disclosure would publish the company’s Equal Employment Opportunity Commission (EEOC) data and describe the company’s ongoing diversity and inclusion programs, instead of proclaiming that the company is a diverse and inclusive workplace. Companies should be aware that all statements made by the company, including those made on the company’s sustainability websites or in ESG reports, are subject to Rule 10b-5 fraud liability under federal and state securities laws.

- **To the extent feasible, collect relevant data and use the data to create quantifiable ESG goals and targets (ESG KPIs).** Collecting ESG data is an important and often overwhelming task of an internal ESG team. Companies may have siloed data across and outside departments of the organization, and need to establish new procedures to collect, organize and report this data, and to establish disclosure controls and procedures to ensure its accuracy. Some companies may need to purchase new software tools or hire consultants to assist with this effort. Focus on the data that is of high-priority to stakeholders and data that is pertinent to the company’s business strategy and easy to collect – Some progress is better than none. Considering the data requirements of reporting frameworks like TCFD or SASB may help companies determine which data is pertinent to their business in light of its stakeholder concerns and business strategy. If the company has a long way to go in certain areas, such as poor workforce diversity and inclusion statistics, consult the company’s peer group to see whether the company’s peers are disclosing this information and, if so, how the company measures up. Carefully weigh the costs and benefits of disclosure of a company’s internal ESG data, goals and process, and make plans to remediate identified ESG deficiencies.

Some ESG data that may be useful for life sciences companies:

1. E – Environmental

1. GHG emissions
2. Number of LEED-certified properties
3. Number of green internal projects, such as number of properties retrofitted with solar panels or number of trees planted through a company Arbor Day activity

4. Waste generated by corporate operations and reduction percentage
5. Number of products accepted for reuse or recycle
6. Number of new sustainable products
7. Water consumed by corporate operations and reduction percentage

2. S – Social

1. Workforce turnover statistics
2. EEO-1 or other workforce diversity statistics, including diversity of management
3. Employee pay equity statistics
4. Clinical trial diversity statistics
5. Number of drug or product recalls issued
6. Number of fatalities related to products as reported by the FDA
7. Number of FDA enforcement actions in response to violation of Good Manufacturing Practices (cGMP)
8. Weighted average rate of net price increases for products to the annual increase in the US Consumer Price Index

3. G: Governance

1. Total dollar financial commitment towards ESG
2. Total dollar amount of losses associated with failures of ESG, such as environmental claims, workplace harassment or discrimination claims, cybersecurity incidents, false marketing claims or product safety claims

- **If the company is not currently tracking ESG data or lacks internal resources to dedicate to the collection and verification of ESG data, consider utilizing third-party data.** Some third-party data providers, such as ESG ratings providers, have analyzed the environmental risks (including having conducted a detailed physical risk analysis), projected GHG emissions and Paris alignment and projected carbon pricing scenarios of publicly traded companies using estimated data and modeling, even if the company has published limited or no ESG-related information. While companies should not rely on these third-party estimates, which may have been gathered using flawed assumptions or other flawed methods, they may be useful tools for understanding how climate change and climate transition may impact the business in the short, medium and long-term, and to inform the company's ESG governance and priorities, particularly in cases where the company has not yet devoted resources to wrangling and reporting ESG data.

- **Include appropriate disclaimers.** Generally, voluntary ESG reports contain forward-looking statements and providing forward-looking statement language may protect the company from liability under securities laws. Additionally, voluntary ESG reports should include language distancing the report's content from financially material information, as discussed in the next bullet.

- **Avoid the use of "material."** To avoid confusion with the SEC concept of financial materiality, voluntary ESG reports should use words like "priorities" or "key issues" rather than "materiality," even if ESG professionals and consultants use the words "material" or "materiality assessment."

- **Take small steps and don't let the perfect be the enemy of the good.** It generally takes over a year (and sometimes longer) to conduct an ESG materiality analysis, engage stakeholders and develop the infrastructure needed to capture and track ESG KPIs. Most companies develop increasingly sophisticated ESG disclosures over a period of time, beginning with small steps, namely, formulating an ESG committee and articulating the company's ESG governance practices.

II. SCALING TO MORE SOPHISTICATED ESG DISCLOSURE

As mentioned above, companies should take steps towards improved ESG disclosures, even if small. As a company's ESG programs mature, they may supplement their reporting with more sophisticated ESG disclosure tools and methodologies, including (i) ESG or sustainability websites, (ii) climate scenario analysis, (iii) ESG KPIs and science-based targets, (iv) independent assurance statements or other independent audits, certifications or verifications, and (v) ESG reporting frameworks.

- **ESG and Sustainability Websites:** A sustainability website provides a digital medium to share sustainability information with investors, employees, customers and other key stakeholders. These sustainability websites may include subjects such as diversity, environmentalism, social impact projects and other sustainability-related topics. Companies that produce annual sustainability reports generally post these on a dedicated sustainability website, and some companies include additional information on this website, such as ESG-related news and press releases and progress towards ESG KPIs.

- Climate Scenario Analysis:** A climate scenario analysis is a well-established quantitative methodology that considers a range of hypothetical scenarios – such as a risk assessment of physical risks to a company's manufacturing facilities, or manufacturing facilities of a company's suppliers, at an increased future climate temperature (over pre-industrial temperature) of 1.5°C (lower risk scenario), 2°C (medium risk scenario), and 3°C (high risk scenario). Generally, environmental engineers conduct climate scenario analyses, which are highly technical, rely on hypotheticals and assumptions, and may involve the use of differential equations. This form of risk management analysis could include any number of scenarios, such as analyzing physical risks, potential temperature increases or decreases, or a change in demand for a certain energy source. Conducting and reporting on a climate scenario analysis is a key recommendation from the TCFD. However, many companies that conduct climate scenario analyses, including those who use the TCFD framework in their reporting, do not currently include detailed information about their scenario analyses in their sustainability reports, due to their competitively sensitive nature. A recent analysis by DLA Piper ESG Data Analytics found that 9% of life sciences companies studied mentioned conducting a climate scenario analysis in their ESG sustainability reports. One of the most controversial mandates of the SEC's proposed climate change rules is proposed Item 1502(f), which requires detailed disclosures related to scenario analyses conducted by companies that use scenario analyses (underlined text added):

*(f) Describe the resilience of the registrant's business strategy in light of potential future changes in climate-related risks. Describe any analytical tools, such as scenario analysis, that the registrant uses to assess the impact of climate-related risks on its business and consolidated financial statements, and to support the resilience of its strategy and business model. If the registrant uses scenario analysis to assess the resilience of its business strategy to climate-related risks, **disclose the scenarios considered (eg, an increase of no greater than 3 °C, 2 °C, or 1.5 °C above pre-industrial levels), including parameters, assumptions, and analytical choices, and the projected principal financial impacts on the registrant's business strategy under each scenario. The disclosure should include both qualitative and quantitative information.***

Commenters noted that this requirement is overly burdensome and may create a “chilling effect” on the use of climate scenario analyses. In particular, the Society for Corporate Governance noted that scenario analyses are likely to be competitively sensitive, and the rule should provide for the disclosure of the use of climate scenario analysis without requiring disclosure about detailed inputs, assumptions, parameters and outputs.

- ESG KPIs and Science-Based Targets:**

ESG key performance indicators, or KPIs, refer to the data that a company deems relevant to its ESG goals and uses to measure ESG progress. Science-based targets are defined methodologies and practices to measure emissions reductions and net zero targets, such as the Science Based Targets initiative, or SBTi. Some reporting standards like GRI and SASB are designed to encourage the reporting of quantitative ESG KPIs like employee turnover rates and greenhouse gas emissions. Companies with sophisticated ESG programs will generally report on progress towards their ESG goals using ESG KPIs and science-based targets.

- Independent Assurance Statements and Third-Party Audits:**

Independent assurance statements provide third-party verification for a company's ESG disclosure. Many assurance providers, global accounting firms, environmental engineering firms and ESG consulting companies provide independent assurance services for ESG disclosures. The inclusion of this assurance statement serves to validate ESG disclosures and provide standardized information for interested individuals. Generally, companies that provide voluntary independent assurance statements in their ESG reports provide limited assurance of one or more particular datapoints, such as scope 1 emissions data. Among the 40 life sciences companies we analyzed in our 2021-2022 Dataset, 15% provided an independent assurance statement in their most recent annual ESG report.

In addition to independent assurance statements, some companies conduct independent, third-party audits using a recognized framework, such as ISO audits or LEED certifications for properties. Additionally, an increasing number of activist shareholders have been asking companies with diversity and inclusion challenges to perform racial equity audits. ISO and LEED standards are discussed further in the following Section IV.E (“ESG Reporting Frameworks and ESG Ratings”).

E. ESG Reporting Frameworks and Ratings

Sanjay Shirodkar, Brooke Goodlett and DLA Piper ESG Data Analytics

I. ESG REPORTING FRAMEWORK BASICS

ESG reporting standards are frameworks used by companies to account for environmental, social, and governance issues. Using the guidelines that these ESG frameworks provide, companies can decide the types of topics to communicate and how to communicate them effectively. Reporting frameworks may also help validate the claims made in ESG reporting. A company can identify suitable frameworks to report and measure its ESG progress.

Different kinds of frameworks can serve different purposes pertaining to a sector or practices of a company. Some frameworks, such as the SASB and GRI, broadly encompass various aspects of ESG, while some standards target specific ESG issues. For example, the TCFD assesses climate related risks, while the Wildlife Habitat Council (WHC) assesses conservation and biodiversity related risks, and the CDP assesses climate, conservation and biodiversity related risks. The Task Force for Inequality-Related Financial Disclosures (TIFD) assesses inequality. A company need not pick a single framework- each serve a different purpose and many companies report under multiple frameworks.

Key ESG Reporting Frameworks found in Life Sciences Sector



Value Reporting Foundation / Sustainability Accounting Standards Board (SASB)

Focus: Financially-material ESG issues; Sector-Focused

Year Founded: July 2011

Organizing Body: Value Reporting Foundation Board of Directors

Widely used in life sciences ESG reports? Yes

SASB's purpose is to disclose information related to ESG more broadly that also impacts financial statements. SASB was merged into the Value Reporting Foundation and is being merged into the IFRS's new ISSB.

SASB's focus on sectors and financial statement impact are helpful for a US company to assess pertinent ESG risks. A more thorough discussion of SASB standards, now part of the ISSB (but remaining as a stand-alone framework as well), is included in Section II.A ("What Do We Mean By 'ESG?'").

From website: "SASB Standards guide the disclosure of financially material sustainability information by companies to their investors. Available for 77 industries, the Standards identify the subset of environmental, social, and governance (ESG) issues most relevant to financial performance in each industry."



The International Sustainability Standards Board (ISSB)

Focus: Sustainability

Year Founded: November 2021

Organizing Body: International Financial Reporting Standards (IFRS) Foundation

Widely used in life sciences ESG reports? No (standards to come)

In November 2021 at the Glasgow COP26 meetings, the IFRS Foundation announced the creation of a new International Sustainability Standards Board (ISSB) "to develop – in the public interest – a comprehensive global baseline of high-quality sustainability disclosure standards to meet investors' information needs." This initiative was in line with commitments from leading sustainability organizations to execute an integration of the Climate Disclosure Standards Board (CDSB), an extension of the CDP, and the Value Reporting Foundation (VRF), which encompasses both the Integrated Reporting Framework and the Sustainability Accounting Standards Board (SASB) standards by June of 2022. In August of 2022 the IFRS Foundation officially announced the unification of the VRF to begin the work of developing the ISSB's sustainability disclosure standards. ESG industry insiders are continuing to monitor these developments.

From website: "The intention is for the ISSB to deliver a comprehensive global baseline of sustainability-related disclosure standards that provide investors and other capital market participants with information about companies' sustainability-related risks and opportunities to help them make informed decisions."

Key ESG Reporting Frameworks found in Life Sciences Sector



Global Reporting Initiative (GRI)

Focus: Sustainability

Year Founded: 1997

Organizing Body: Roots involve the organizations CERES, the Tellus institute, and the UN Environment Programme.

Widely used in life sciences ESG reports? Yes

Unlike SASB and ISSB, which focus on financial materiality, GRI focuses on “double materiality” and a company’s impact on the greater world.

From website: “Our mission and history: GRI envisions a sustainable future enabled by transparency and open dialogue about impacts. This is a future in which reporting on impacts is common practice by all organizations around the world. As provider of world’s most widely used sustainability disclosure standards, we are a catalyst for that change.

WHY: GRI exists to help organizations be transparent and take responsibility for their impacts so that we can create a sustainable future.

HOW: GRI creates the global common language for organizations to report their impacts. This enables informed dialogue and decision making around those impacts. WHAT: We are the global standard setter for impact reporting.

We follow an independent, multi-stakeholder process. We maintain the world’s most comprehensive sustainability reporting standards. Our Standards are available as a free public good.”



Task Force on Climate-Related Financial Disclosures (TCFD)

Focus: Climate Change: Carbon Related Assets and Risks; Financial Materiality

Year Founded: December 2015

Organizing Body: TCFD was established by the Financial Stability Board (FSB).

Widely used in life sciences ESG reports? Yes (most common)

The TCFD’s purpose is to disclose information that is material to financial statements and related to climate change.

From website: “The Financial Stability Board established the TCFD to develop recommendations for more effective climate-related disclosures that could promote more informed investment, credit, and insurance underwriting decisions and, in turn, enable stakeholders to understand better the concentrations of carbon-related assets in the financial sector and the financial system’s exposures to climate-related risks.”



Taskforce on Nature-related Financial Disclosures (TNFD)

Focus: Nature

Year Founded: January 2019

Organizing Body: The TNFD will build upon the structure and foundation of the Task Force on Climate-related Disclosures (TCFD)

Widely used in life sciences ESG reports? No

TNFD is an emerging framework for reporting on nature-related risks.

From website: Our mission: “To develop and deliver a risk management and disclosure framework for organizations to report and act on evolving nature-related risks, which aims to support a shift in global financial flows away from nature-negative outcomes and toward nature-positive outcomes.”



Taskforce on Inequality-related Financial Disclosures (TIFD)

Focus: Inequality

Year Founded: February 2021

Organizing Body: The TIFD is inspired from the TCFD and aligned with the SDGs.

Widely used in life sciences ESG reports? No

TIFD is an emerging framework for reporting on inequality-related risks.

From website: “TIFD is conceived as an explicit systemic risk management framework that can reduce inequality created by the private sector. A collaboration among investors, civil society, businesses, financial regulators, policy makers, and academics, TIFD will provide guidance, thresholds, targets, and metrics for companies and investors to measure and manage their impacts on inequality, as well as inequality’s impacts on company and investor performance.”

Key ESG Reporting Frameworks found in Life Sciences Sector



CDP (Formerly Carbon Disclosure Project)

Focus: Climate change, water security and deforestation

Year Founded: 2000

Organizing Body: CDP Global is an international non-profit organization comprising of CDP Worldwide Group, CDP North America, Inc. and CDP Europe AISBL.

Widely used in life sciences ESG reports? Yes

The CDP evaluates the environmental impact of companies and cities across three metrics: water security, forests, and climate change. Life Sciences companies can complete and submit a CDP questionnaire, which will be scored and posted online for anyone to view. Because the CDP questionnaire covers comprehensive data points, the website offers a place to store data, realize progress over time, and uncover risks and opportunities. Because the CDP is a globally recognized standard body, life sciences companies can work with the CDP to boost their reputation as environmentally contentious and active.

From website: "CDP is a not-for-profit charity that runs the global disclosure system for investors, companies, cities, states and regions to manage their environmental impacts. The world's economy looks to CDP as the gold standard of environmental reporting with the richest and most comprehensive dataset on corporate and city action."



Sustainable Development Goals (SDGs)

Focus: Sustainability and Human Rights

Year Founded: 2015

Organizing Body: UNDP is part of the UN development system (UNDS) and works with UN Resident Coordinators, and as a part of UN Country.

Widely used in life sciences ESG reports? Yes

The United Nations Sustainable Development Goals (UN SDGs) are a set of 17 goals that were designed by the United Nations to promote peace within the world as well as ensure more sustainable business practices. Including metrics like No Poverty, Zero Hunger, Good Health and Well-Being, Quality Education, and Gender Equality, the goals are focused on creating a better society. These metrics are further displayed in an Agenda for Sustainable Development as well as annual implementation reports, located on the UN's website.

From website: "The SDGs must be implemented in an integrated way to help countries tackle complex challenges and lay out a more sustainable future."

"That is why UNDP is focusing on SDG integration, an approach to development that targets systems – not just thematic sectors – to address all aspects of a complex challenge, including its root causes and its ripple effects across economies, societies and natural ecosystems."



Leadership in Energy and Environmental Design (LEED)

Focus: Green Building

Year Founded: 1993

Organizing Body: U.S. Green Building Council (USGBC) promotes sustainability in building design, construction, and operation.

Widely used in life sciences ESG reports? Yes

LEED certification is an important standard for real estate.

From website: "The most widely used green building rating system in the world. Available for virtually all building types, LEED provides a framework for healthy, highly efficient, and cost-saving green buildings."



International Organization for Standardization (ISO)

Focus: Development and education about global standards

Year Founded: 1946

ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies

Widely used in life sciences ESG reports? Yes

ISO standards cover a wide array of activities from health and safety to Information and Technology security. The following ISO standards may be useful in verifying a company's ESG performance:

- 26000 provides guidance on CSR or corporate social responsibility (respecting society and the environment) and assesses an organization's commitment to sustainability and its overall performance.

- 9001 addresses quality management systems and helps customers get consistency and high-quality from their goods and services.

- 14001 sets out the criteria for an environmental management system and provides assurance that the environmental impact of a company's management and employees are being measured.

- 14005 provides flexibility and accessibility to companies by setting guidelines to implementing environmental management systems in phases, such as establish, implement, maintain, and improve with ISO 14001 as an end-goal.

- 45001 creates standards for reducing workplace hazards and risk.

Key ESG Reporting Frameworks found in Life Sciences Sector

-50001 addresses energy management systems to help organizations systematically improve their energy performance. Life sciences companies that use the ISO standards can create benchmarks, track and improve themselves over time, and boost their consumers' confidence that their products are of high quality, safe, and reliable. In addition, external auditing firms can assess a company's compliance with ISO standards.

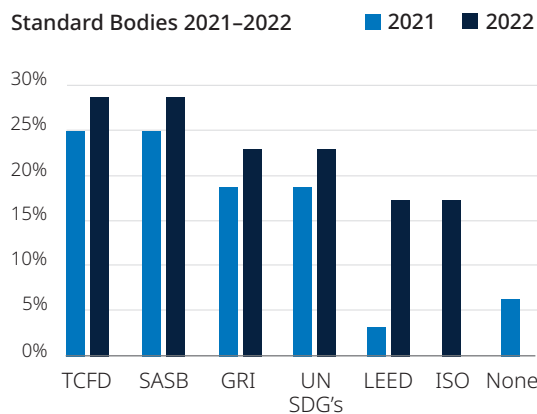
From website: "We're a global network of the world's leading standardizers. Through our members we bring together experts from all over the world to develop International Standards."

Since 2019, DLA Piper ESG Data Analytics has tracked the use of reporting frameworks in sustainability reports of life sciences companies. Below follows an analysis of ESG framework usage trends in the life sciences sector.

II. SHORT-TERM REPORTING FRAMEWORK TRENDS: 2021-2022

We analyzed the usage of ESG reporting frameworks, where applicable, by the 40 life sciences companies in our 2021-2022 Dataset. The only standard bodies used in these years were: the Task Force on Climate-Related Financial Disclosures (TCFD), the Sustainability Accounting Standards Board (SASB), the United Nations Sustainable Development Goals (UN SDG's), the Leadership in Energy and Environmental Design (LEED), the Global Reporting Initiative (GRI) and the International Organization for Standardization (ISO).

- TCFD and SASB were the most commonly mentioned standard bodies in both 2021 and 2022.
- In 2021 25% of analyzed companies mentioned both TCFD and SASB, and this number increased slightly in 2022 to 28%.
- The presentation of LEED and ISO was not tracked by our methodology until late 2021, but in 2022, these frameworks were used by 23% of analyzed companies.
- Usage of GRI and UNSDs slightly increased from 19% to 23%.

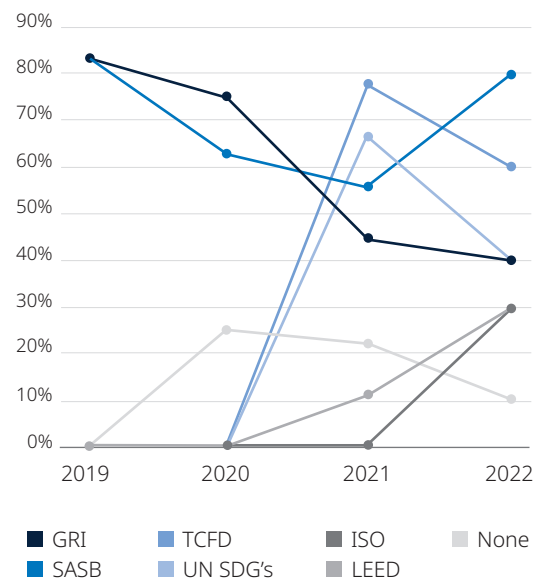


III. FOUR-YEAR REPORTING FRAMEWORK TRENDS: 2019-2022

We analyzed the usage of ESG reporting frameworks, where applicable, by the 15 life sciences companies in our 2019-2022 Dataset. The total number of frameworks used increased from 10 to 28. The only standard bodies mentioned by the companies were TCFD, SASB, UN SDGs, LEED and ISO.

- While GRI and SASB were the only mentioned standard bodies in 2019 and 2020, different standard bodies gained usage by 2022.
- In 2021, TCFD and the UN SDGs were also mentioned, with TCFD ranking most commonly mentioned with 78% of companies with an ESG report utilizing TCFD, followed by the UN SDGs at 67%, SASB at 56% and GRI at 44%.
- In 2022, SASB became the most commonly used standard body at 80% usage by companies with an ESG report, followed by the TCFD at 60%, then GRI and the UN SDGs each at 40%, and lastly ISO and LEED at 30%.

Standard Bodies 2021-2022



Much like ESG reporting frameworks, ESG ratings providers generally serve distinct purposes and have distinct agendas.

IV. ESG RATINGS AND QUESTIONNAIRES

ESG ratings, which are distinct from ESG credit ratings, which are discussed further in Section VIII.A.VI (“ESG Credit Ratings”), relate to ESG “grades” assigned by third parties. Much like ESG reporting frameworks, ESG ratings providers generally serve distinct purposes and have distinct agendas. Some, but not all, ESG reporting frameworks also provide ESG ratings. CDP is the most well-known rating agency of the reporting frameworks mentioned in our chart in Section IV.E (“ESG Reporting Framework Basics”). Many ESG ratings agencies, especially the most well-known “Big Four”: S&P Trucost, Morningstar’s Sustainalytics, MSCI and ISS’s R-Factor, are not reporting frameworks, but may rely on a company’s ESG reporting and the use of frameworks to determine a company’s ESG score, among other sources.

Companies may receive frequent requests from investors and third parties to complete questionnaires, surveys, or provide other information to assist with that investor or third-party’s ESG assessment. Generally, ESG ratings are created using a combination of responses to these requests for information and engagement with the company, ESG disclosures publicly available on the company’s website, in ESG reports, SEC filings or even statements made by the company on social media, news articles, endorsements from third parties and other sources.

Resources permitting, companies should answer questionnaires and surveys related to ESG scores important to its investors and other stakeholders. By failing to respond, a company may inadvertently damage their ESG score which may, in turn, impact a company’s qualification for investment by ESG funds, access to capital, ESG reputation or standing in the market. For example, companies that do not participate in the CDP receive an automatic “F” grade from the CDP. Additionally, some of these third parties may be activist shareholders, in particular, agenda-driven shareholders, and ignoring their communications may escalate into an activist campaign.

ESG rating services often have diverse assessment methodologies and may use different inputs or sources for assessing ESG. A JP Morgan study demonstrated that across MSCI and S&P, ESG ratings agreed only 18% of the time. This lack of standardization is influenced by differing priorities, agendas, measurement criteria and available data among the ratings agencies. For instance, some ratings agencies may primarily rely on the robustness of a company’s ESG disclosure while others focus more on environmental or social impact, or both robust disclosure and impact. Some ratings agencies, like CDP, may be primarily concerned with environmental performance while others, like the “Big Four,” consider environmental, social and governance performance. Additionally, some ratings agencies have been criticized for their lack of objectivity. In August 2022, the attorneys general of several states opened an investigation into a major ESG ratings firm for penalizing companies that do business in Israel.

F. ESG Materiality and Tools for Navigating Differing Stakeholder Concerns

Brooke Goodlett and Deborah Meshulam

ESG materiality is a distinct concept from SEC reporting materiality. In an SEC reporting context, a fact is material when there is a substantial likelihood that the fact would have been viewed by a reasonable investor as having significantly altered the total mix of information made available. See *TSC Industries v. Northway, Inc.*, 426 U.S. 438, 449 (1976); *Basic, Inc. v. Levinson*, 485 U.S. 224 (1988). For many companies, when they speak of “ESG materiality,” they are referring to priority ESG goals. Within the ESG sphere, there are two lenses through which to examine materiality: financial and impact materiality.

Financial materiality relates to issues that may materially impact a company’s financial statements or operating results. Financially material issues that have a substantial likelihood of impacting a reasonable investor’s decision to invest in the company might also be material for SEC purposes. Impact materiality relates to ESG issues having a material impact on the external environment

and society at large. Double materiality merges financial and impact materiality. Through this lens, an issue can be considered material for ESG purposes if it relates to one or both lenses. As mentioned in Section IV.E (“ESG Reporting Frameworks and Ratings”), different ESG reporting frameworks serve different purposes. Generally, TCFD and SASB are tailored to respond to financial materiality, while the CDP, GRI and UN SDGs are tailored to respond to impact materiality.

A major criticism of the SEC’s proposed climate rules is that the proposed rules mandate the reporting of immaterial ESG information. For example, the proposed rules would mandate disclosure of climate-related risks totaling 1% or more of a line item in a year’s financial statements. This bright-line 1% rule has been opposed by major accounting firms and such industry organizations as the Society for Corporate Governance and the Council for Institutional Investors in comment letters to the SEC. These organizations argue that this bright-line threshold is arbitrary, burdensome and not useful to investors, and that it should be replaced with a materiality standard or a principles-based approach.

While market participants wait for the SEC’s final rules, various stakeholders remain focused on ESG issues and information. To evaluate and understand such concerns and their potential impact, companies can use a variety of tools to identify ESG priorities and balance competing ESG interests and concerns among its disparate stakeholder groups. These tools include:

- **Stakeholder Engagement:** Stakeholder engagement refers to the process of identifying a company’s key stakeholders and reaching out and communicating with these stakeholders about their most important concerns including, if relevant, ESG concerns.

Publicly traded companies generally engage with stockholders to prepare for annual meetings, and ESG has become a common topic in these conversations. Some major investors and proxy advisory firms have adopted voting policies related to ESG oversight and practices, and it is important that companies are familiar with stockholder priorities and voting policies. Companies can engage with stockholders by completing questionnaires and requests for information from stockholders, hosting an ESG investor day or ESG roadshow, or

regularly addressing ESG at investor meetings. Through engagement, the company can identify its stockholders’ ESG priorities.

As mentioned previously in Section II.C. (“Why Is ESG Important? Activism, Shareholder Proposals and Governance Engagement”), if a company receives a letter or request for ESG-related information from a non-profit or small stockholder, particularly those who have previously conducted shareholder activism campaigns, companies should recognize that this may be the first step in a series of events that could escalate into a shareholder activism campaign. It is wise to have a strategy ready and appropriate resources to respond to these requests.

Because ESG is of importance to not only investors but also other stakeholders, like employees, value chain partners, customers, industry organizations, and the communities in which companies operate, ESG stakeholder engagement can be much broader than stockholder engagement. Identifying which stakeholders are important and whether and how to engage with these stakeholders may be a complex process and will vary from company to company.

Reporting frameworks can be helpful tools when conducting a materiality assessments.

- **Materiality Assessments:** An ESG materiality assessment is the process of using stakeholder engagement, as well as other inputs, such as reporting frameworks, competitive studies and peer group analyses, to identify the ESG issues most important to a business’s stakeholders and evaluating those issues to determine the company’s most important ESG priorities. Some companies refer to an ESG materiality assessment as a “priority assessment” or “key issues assessment” so as not to confuse the concept of ESG materiality with SEC materiality. Companies that conduct ESG materiality assessments typically include a description of this process and its outcomes in their annual ESG report. Additionally, the reporting frameworks discussed in Section IV.E. “ESG Frameworks and Ratings”) above can be helpful tools when conducting a materiality assessments.

- **Competitive Study:** A competitive study refers to a marketing analysis of the sustainability and ESG practices of the company's major competitors, as well as an analysis of trends and preferences related to a company's ESG practices that may impact a company's competitiveness with consumers or in the labor market. Focus groups, employee or customer surveys, or research related to competing company practices are methods of conducting a competitive ESG study.
- **Peer Group Analysis:** A peer group analysis refers to examining ESG disclosures, commitments and performance by a company's competitors and companies of a similar size in the same industry. A peer group analysis can be used to determine if the company has any "gaps" in its ESG reporting or practices (often called a "gap analysis"), peer group ESG norms and how a company measures up in ESG reporting and performance as compared to its peers. DLA Piper's ESG Data Analytics Group frequently performs ESG peer group analyses.

G. Anti-Corruption and Integrity

Brooke Goodlett and Isaiah Larios

Mitigating corruption risk is crucial to the operation of a compliant and sustainable organization. Many governing bodies and jurisdictions have enacted laws such as the US Foreign Corrupt Practices Act, or FCPA, and the UK Bribery Act, targeting corrupt practices within their jurisdictions and creating significant legal penalties for companies engaging in corrupt practices in the United States and abroad. A July 2022 paper by the World Economic Forum, "Investing in Integrity in an Increasingly Complex World: The Role of Anti-Corruption Amid the ESG Revolution," identified anti-corruption as an important part of the ESG framework for investors.

Corruption creates a substantial financial risk for organizations due to exposure to fines from a violation of anti-bribery and anti-corruption laws, dishonest financial reporting, unsustainable financial practices, and reputational damage. Additionally, corruption can damage the environment or society through prioritizing short term financial gain over sustainability and incentivizing decreased accuracy in impact reporting. The human rights impact of corruption is substantial due to the undermining of regulatory enforcement

and the potential redirection of funds away from social programs where the bribery takes place. The World Economic Forum has reported that corruption can be the inspiration for governments to ignore or facilitate the violation of human rights.

Companies building a culture of compliance should seek to build a culture of corporate integrity through internal initiatives and rehauls of policies, processes, and training for employees to recognize and avoid corrupt practices and for management to oversee and monitor potentially corrupt behavior within the organization.

A considerable challenge for global companies is navigating cross-cultural business norms. In the United States where there is a long precedent of anti-corruption law, bribery, and corruption are treated as serious business threats. However, other countries may have differing business norms and "quid-pro-quo" business dealings and other illegal practices may not have the same stigma and legal ramifications as in the United States. Different cultures, within the United States and abroad, may have differing concepts of ethical behavior, honesty, fair dealing, elevating questionable practices to superiors or whistleblowing. Global companies seeking to build a culture of ethics and integrity that goes beyond compliance should understand these cross-cultural challenges, which can be overcome by ensuring that new and existing employees worldwide are trained to understand the company's culture and policies, ensuring that this training is repeated, monitored and improved and by empowering and encouraging employees to collectively promote a culture of ethics and integrity.

H. Guidelines for Adopting Effective Controls and Risk Management for ESG

David Peyman

Companies are increasingly recognizing the need to address ESG risks and implement effective controls to measure ESG data and incorporate ESG risk factors in business decision-making. While some companies have established processes and dedicated significant resources to identify and quantify ESG risk, they have not necessarily incorporated such risk factors into business decision making. Accordingly, ESG has been used to inform business decisions more than to guide

them. Institutionalized due diligence procedures and key performance indicators can assess and monitor ESG risk, and how such risk changes over time in order to inform investors, stakeholders, and business decision making. Incorporating ESG data in investment decisions may not always be consistent with achieving the highest returns, yet identification and assessment of such risks may lead to long-term changes in behavior both for the investor and investment target. Companies can consider the risks and rewards of publishing ESG data versus maintaining confidentiality of such data and using the data to engage in discussions with counterparties to mitigate ESG risk in meaningful ways.

Some objectives for companies to consider when implementing internal controls include:

- **Relevance of Data** – Does it matter to key stakeholders and meet their needs?
- **Completeness and Accuracy of Data** – Does the data have a clearly defined scope with consistent criteria for measurement and evaluation? Has the company adopted appropriate procedures to collect, organize, report, monitor and verify data housed within differing silos inside and outside the company?
- **Timeliness of Reporting** – Do procedures support the collection and verification of data on the needed timeframe? How may new laws, such as the proposed SEC climate rules, impact these time frames?
- **Data Protection and Security** – Does the company have security vulnerabilities related to the data and how might the company mitigate these vulnerabilities?
- **Approval and Authorization** – Are internal controls approved and authorized by the appropriate levels of management? Are data collection and controls given appropriate attention and priority by employees and their managers? Is the company's internal audit and disclosure committee involved with the data collection and verification and review of existing disclosure controls and procedures?
- **Education and Acceptance** – Are employees trained to implement internal control procedures and are the internal controls designed to ensure widespread adoption within an organization?

Along with establishing internal controls, implementation of an ESG risk management process can help companies prepare for and mitigate long-term risks, identify ESG opportunities and maintain strong investor relations by:

1. Considering how ESG plays a role in the long-term growth of the company and addressing shareholder concerns
2. Identifying material ESG risks
3. Assessing the potential impact of ESG risks in respect to financial, regulatory and reputational outcomes
4. Determining how ESG plays a role in strategic decision making and company goals and
5. Assessing the effectiveness of ESG-related controls and usefulness of an ESG program.

An ESG risk management process is not a one-size-fits-all approach, and companies will benefit more by tailoring the process to their unique financial objectives, constituents, procedures and strategic goals. Companies should be wary of a “check-box compliance culture” and ensure that all employees, including ESG staff, have an ESG risk mindset that aligns with consistent and accurate ESG disclosure.

I. ESG Due Diligence in M&A and Venture Capital

Brian Wohlberg, Brooke Goodlett and UTGSLI

An increasing number of acquirers and investors are conducting ESG-related due diligence in mergers and acquisitions (M&A) and venture capital (VC) in both the public and private sectors. Specifically, given that many socially and environmentally impactful companies are also those that are developing innovative solutions to challenges in health and society, ESG is just as important in the context of life sciences M&A and VC. While due diligence has long focused on assessing practices and risks associated with compliance with environmental laws, labor laws, truth-in-advertising laws and other legal regimes that relate to ESG, given several high-profile scandals at companies that were originally backed by venture capital, “ESG due diligence” generally relates to investigating how a target company is overseeing and managing ESG, the target company's existing ESG practices and policies, and whether the target company meets the investor or acquirer's ESG expectations and practices, such as a VC's commitments to investing in accordance with the United Nations' Principles for Responsible Investment, and those of major customers and other key industry players.

While ESG due diligence was once mostly confined to public acquisitions, private-deal acquirers and investors, especially in the United Kingdom and Europe, are more frequently evaluating target companies' performance related to ESG factors, particularly as companies comply with existing and proposed supply chain due diligence regulations in the European Union. Acquirers and private investors in private M&A may also reassess a deal's risks and transaction value as a result of ESG due diligence. For example, acquirers and private investors may investigate ESG synergies and evaluate whether a target will negatively or positively impact its brand, credit rating, ESG ratings, ESG commitments and ESG KPIs. ESG due diligence can be broad or narrow in scope, and should be tailored to the parties' material ESG risks, ESG strategy and ESG goals. Additionally, due diligence should encompass ESG-specific questions and should contain various ESG criteria that feed into final decisions. Since April 2021, DLA Piper has partnered with ESG risk management and data platform Datamaran to integrate ESG due diligence into legal due diligence.

J. Integrating ESG into Executive Compensation

Rita Patel and Mary Claire Blythe

ESG metrics are quickly becoming a more popular measure for not only evaluating public company performance, but also for compensating public company executives through performance-based equity awards. Specifically, the number of equity-based awards that become vested or earned by the executive is based on one or more ESG factors.

Public companies grant equity awards, particularly performance-based equity awards, as a method to incentivize and retain its executive leadership team, also known as "pay for performance." Historically, public company executives earned their performance-based compensation based on criteria that generally has a direct impact on company success and share value, such as revenue, EBITDA, and total shareholder return (TSR). With an increased emphasis from certain institutional shareholders with respect to ESG practices, public companies are now beginning to link ESG performance to executive pay.

However, granting performance-based awards to executives subject to ESG performance comes with various issues that public companies need to be aware of prior to granting such awards. These issues include:

1. Determining Appropriate Performance Targets.

Unlike company revenue, TSR, and EBITDA, ESG factors may not be as easily quantifiable. Therefore, it may be difficult for a company to determine the appropriate goals or targets that the executive should strive to achieve in order to vest in the executive's performance awards. Targets should be attainable so that the award still provides the company the ability to incentivize and retain its executive team but also cannot be so easily achievable that the award is viewed negatively by shareholders as excessive pay and not "pay for performance."

2. Determining Length of Performance Period: Performance-based Awards for Public Companies.

In connection with determining whether a performance target will be achievable, companies also need to consider the time period that the executive has to achieve such targets. Currently, the average length of a performance-based award is three years. Three years provides the company some assurance of retention while also providing the executive time to achieve targets even if there is a market downturn in one calendar year. Three years may not be long enough, however, to measure ESG performance depending on the specific ESG measure used. Certain ESG factors, such as environmental goals or the company being carbon neutral, could take far longer than three years to achieve or even take longer than three years to see progress towards such performance targets.

3. Measuring Performance Achievement.

ESG performance may not be quantifiable and accordingly, may be difficult to determine when performance is actually achieved. It is important for companies to consider making ESG performance targets with specificity in order to provide clear guidance on when such performance targets have been met. In addition, a company should consider whether to give its board of directors or compensation committee the discretion to certify the performance level achieved or to adjust performance in the event that any ambiguity or difficulties arise in measuring performance achievement.

4. Determining Level of Pay Linked to ESG

Performance. In addition to determining the appropriate ESG performance measures and performance period, another critical factor is determining the appropriate level of executive pay out if such performance is actually achieved. In connection with the “pay for performance” compensation strategy, the level of pay should align with the value added by the executive in company performance and shareholder value in achieving such ESG performance targets. If an ESG performance target is easily achievable or achievable without much involvement by the executive, a large pay out may be viewed negatively by shareholders as excessive compensation.

5. Disclosure of Performance Measures. Beginning with fiscal years ending on or after December 16, 2022, most public companies must disclose in their annual proxy statements an additional table disclosing the relationship between executive compensation and financial performance. Companies will need to consider this additional table when determining whether and which ESG factors should be used for granting performance-based awards to its executive team.

K. Board Diversity

Brooke Goodlett and Louann Fang Richard

Diversity of a company's board of directors remains a primary concern of employees and traditional governance-minded investors. In 2014, the New York City Comptroller launched the “Boardroom Accountability Project,” seeking to improve disclosure and promote board diversity. Additionally, the major proxy advisory firms ISS and Glass Lewis have in recent years adopted increasingly insistent board diversity-related voting guidelines. In December 2022, ISS and Glass Lewis announced policy updates on the topic of board diversity for the 2023 proxy season. ISS will generally recommend against the chair of the nominating and governance committee if there are no women on the board. Additionally, Glass Lewis will recommend against the chair of the nominating and governance committee if the company is a Russell 3000 index company and the board is not at least 30% gender diverse or if the company is outside of the Russell 3000 index and the board is all-male. Additionally, for Russell 1000 index companies, Glass Lewis will generally recommend against the chair of the nominating and

governance committee of a board with fewer than one director from an underrepresented community. Glass Lewis defines “underrepresented community” as an individual who self-identifies as Black, African American, North African, Middle Eastern, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaskan Native, or who self-identifies as gay, lesbian, bisexual, or transgender. For the purposes of this evaluation, Glass Lewis relies solely on self-identified demographic information as disclosed in company proxy statements. Additionally, Glass Lewis may recommend that shareholders vote “for” directors if the board provides sufficient rationale or a plan to address its lack of diversity. Glass Lewis considers a companies’ diversity disclosures and for companies in the Russell 1000 index, Glass Lewis will generally vote against the chair of the nominating and corporate governance committee if the company fails to provide adequate board diversity disclosure or has not provided disclosure of individual or aggregate racial/ethnic minority demographic information.

Further attention has been called to the issue of board diversity through recent rule changes and legislation and this may be an area of focus for traditional asset managers in the next few years. The new Nasdaq Stock Market LLC (Nasdaq) board diversity disclosure rules for which compliance began in 2022 require Nasdaq-listed companies to annually disclose information about the board's voluntarily self-identified gender, racial characteristics and LGBTQ+ status in a matrix format as well as to include, or disclose why they have not so included, a certain number of diverse directors by 2023. Although California's gender board diversity law, California Corporations Code Section 301.3 (SB 826), was recently held unconstitutional (and a similar law requiring racial board diversity was struck down earlier this year), they are examples of legislation that reflect the growing expectation that public companies have diverse boards.

L. Public Benefit Corporations

Brooke Goodlett and Annette Moreno

A company that considers ESG “mission critical” may seek to incorporate as a public benefit corporation. Public Benefit Corporations (PBC) are hybrid, for-profit corporations that have legal obligations to commit to higher standards of purpose, accountability and transparency. PBCs must (i) pursue a general or specific

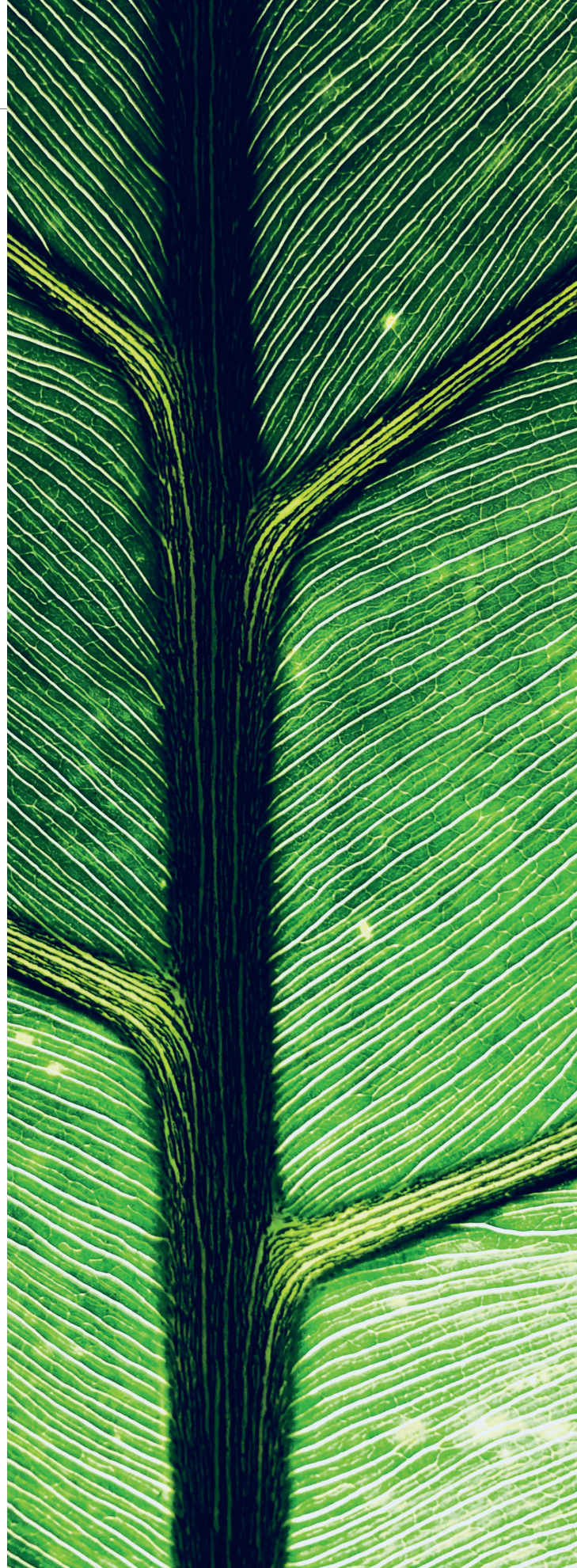
public benefit, (ii) consider the non-financial interest of its shareholders and other stakeholders when making decisions, and (iii) report how they are achieving their overall public benefit objectives. The directors of a PBC have an expanded responsibility to manage the company in a manner that would balance those interests provided above, along with the public benefits identified in the company's certificate of incorporation. There are 15 publicly traded public benefit corporations as of December 31, 2022. About 26% (4/15) of the companies were in the life sciences sector.

There are some advantages to becoming a PBC: the satisfaction of having a socially responsible corporate mission, access to capital from impact funds or other socially-responsible funds and the branding and marketing advantages that come with a PBC designation. However, even companies that consider ESG to be "mission critical" may choose to pursue their business strategy through traditional corporate forms, such as a C-Corporation, and not through a PBC. Some disadvantages of PBCs include: PBCs are challenging to form and maintain and require extensive reporting requirements, which are described below, PBCs are not available in every state, and directors of PBCs are subject to extended liability related to the company's ESG mission, reporting and goals.

To form a PBC, a specific public benefit purpose clause must be included in the company's certificate of incorporation. Existing corporations are also able to file an amendment to become a public benefit corporation, however, there are certain requirements. Those requirements include filing an amendment to the certificate of incorporation which portrays the company as a public benefit corporation and includes a statement to that effect. This amendment must be approved by the board of directors of the company, and then be approved by the stockholders. Once the amendment has been approved it must be filed with the Secretary of State.

PBCs are sometimes called B Corps. B Corps and PBCs are distinct terms that are often used interchangeably, but there are clear differences. A B Corp is a certification provided to eligible companies by the nonprofit B Labs. The main differences between the two is that a B Corp is available to every business regardless of corporate structure, state or county of incorporation and B Labs is a certifying body offering access to the Certified B Corps logo, a portfolio of services, and the vibrant B Corps community. A PBC, on the other hand, is a particular legal form.

Overall, the main reason to become a PBC is to further a public benefit that is meaningful to the company. In the life sciences sector, a PBC can use science to create breakthroughs that could have a positive social or environmental impact. However, choosing to incorporate as a PBC comes with many obligations and risks, and should be carefully weighed against other alternatives.



V. E: Environment

A. Climate Change and Net Zero Commitments

Jesse Medlong, Alberto Corona, Erin Heiferman and Amanda McCaffrey

Anthropogenic climate change now poses perhaps the greatest environmental threat to humanity's continued survival and success on the planet. Climate change poses physical risk to businesses' operations and systemic risks to their supply chains. As explained further in Section VII ("ESG Risks") and Section VIII ("ESG Opportunities"), enterprises that fail to keep up with the fast pace of change will likely experience difficulty obtaining insurance and finance, and they risk falling behind in the energy transition as regulators, investors, and consumers demand greater action.

Although government efforts remain vital to addressing climate change, a growing consensus recognizes a key role for private companies as well. According to the Intergovernmental Panel on Climate Change (IPCC), achieving the Paris Agreement's goal of limiting global temperature rise to 1.5°C will require economic transformation on a scale never before seen, and many companies have pledged to do their part by committing to drastically reduce their GHG emissions in the coming decades. This will require the development of massive energy projects to fuel manufacturing processes and power server farms.

Technological innovations are vital to decarbonization, and new technology could mitigate climate change or assist in adapting to a changing climate. As we describe more in the Section VIII.B. ("Emerging Breakthroughs in Life Sciences that Could Create a More Sustainable Future"), life sciences advancements like genome editing could be used to create biofortified crops and other species that are more adaptive to changing environment.

B. Deforestation and Biodiversity Commitments

Jesse Medlong, Alberto Corona, Erin Heiferman and Amanda McCaffrey

The abundance and variety of natural resources is critical to the life sciences sector. Like any technology-heavy sector, this includes such geological resources as rare earth metals for electronic components and fossil fuels to power manufacturing processes. More critically, however, is the sector's reliance on the living world for insights and breakthroughs related to developing new treatments and cures and discovering new compounds. For instance, with a majority of new drugs derived from or inspired by natural substances, biodiversity is fundamental to continued innovation in the sector. Collapsing biodiversity thus threatens new drug discovery and creates reputational and legal risks for companies that fail to identify, disclose, and mitigate related risks. The World Wildlife Fund's 2020 "Living Planet Report" reports that the world has seen an average 68% drop of mammal, bird, fish reptile and amphibian populations since 1970. Different regions of the world experience environmental impacts at different rates- Latin America and the Caribbean, for example, has seen a 94% biodiversity loss since 1970, while Europe and Central Asia have experienced a 24% biodiversity loss over the same time period. Additionally, a recent National Geographic article noted that since 1990, the world has lost about a billion acres of forest- mainly in Africa and South America.

Life sciences businesses must also be aware of their own impacts on the natural environment. Manufacturing processes and research and development in the life sciences sector may require raw materials whose extraction can displace endangered wildlife, have profound impacts on local communities, particularly with respect to indigenous peoples, or raise human rights concerns. For instance, sector activities that contribute to forest loss not only threaten biodiversity but also exacerbates climate change. Through partnerships with community stakeholders, life sciences companies can develop strategies for

combating climate and heat pollution and creating and preserving green spaces to counteract the sector's environmental impacts.

As we describe more in Section VIII.B (“Emerging Breakthroughs in Life Sciences that Could Create a More Sustainable Future”), the life sciences sector is at the forefront of research and development of technologies that can create a more sustainable world. For example, cloning and stem cell technology could be used to promote species diversity.

C. Water and Waste Management

Jesse Medlong, Alberto Corona, Erin Heiferman and Amanda McCaffrey

Water is as essential to the life sciences sector as it is to life itself. Companies are increasingly implementing internal initiatives to reduce water consumption and prevent water pollution and other related environmental impacts. Solid waste is another key consideration for the sector, with many life sciences products being inherently single-use and often packaged in plastic—a growing concern in its own right. Both startups and established brands are betting on sustainability innovations in materials science and waste management. Companies in the life sciences sector also contribute significantly to plastic and other wastes. For instance, life sciences laboratories produce around 5.5 million tons of plastic each year. Addressing these environmental wastes requires companies in the life sciences sector to find and deploy alternative substances for packaging and components, such as PE or PET made from sugarcane, post-consumer regrind (PCR), biodegradable products, and polylactic acid. But sector companies must take steps to prevent biodegradable plastics from contaminating traditional recycling systems. Alternatively, companies can reduce plastic use by redesigning their products to require less plastic, incorporating materials such as cardboard and stainless steel.

As we describe more in Section VIII.B (“Emerging Breakthroughs in Life Sciences that Could Create a More Sustainable Future”), the life sciences industry may develop or discover new technologies that could improve global water and waste management, like *Ideonella sakaiensis* 201-F6, a new strain of bacteria that might be used to “eat” plastic.

D. EU and UK Rulemaking

Teresa Hitchcock, Jesse Medlong, Alberto Corona, Erin Heiferman and Amanda McCaffrey

The Corporate Sustainability Due Diligence law proposed by the European Commission would require companies to confirm that their suppliers respect certain environmental standards, and it would oblige directors of companies in the EU to align their business strategies to conform with the goal of limiting global warming to 1.5 Celsius – the more ambitious of the Paris Agreement’s long-term temperature goals. The UK is implementing provisions in the Environment Act 2021 which will require companies across all sectors to provide information regarding the resource efficiency of their products. These and similar regulations emerging around the world will tend to hit industries and sectors with the most expansive or complex supply chains—the life sciences sector among them.

E. Proposed SEC Climate Disclosure Rules and SEC ESG Guidance and Enforcement

Alan Seem and Brooke Goodlett

Disclosure regarding ESG-related issues has historically been made mostly on a voluntary basis with little guidance or standards being offered by the SEC staff. In February 2010, the SEC published its “Commission Guidance Regarding Disclosure Related to Climate Change” to provide guidance to public companies regarding the (then limited) disclosure requirements as they apply to climate change matters. This interpretive guidance prompted companies to analyze how they should approach and consider climate change issues (including the regulations being adopted to address climate change) that could affect their business and operations, either directly or indirectly. Since then, concerns regarding climate change and its impact on all aspects of the economy, and society generally, have increased year by year.

In September 2021, the SEC’s Division of Corporation Finance published a “Sample Letter to Companies Regarding Climate Change Disclosures.” This sample letter set forth examples of typical, representative comments from the SEC staff in the two sections of disclosure where climate change-related issues most commonly arise, namely the Risk Factors and

Management's Discussion and Analysis of Results of Operations and Financial Condition. Since then, dozens of publicly traded companies have received similar comment letters from the SEC. The sample comment letter refers back to the February 2010 interpretive guidance and, as is typical, asks the issuer to either revise its disclosure or provide requested information, or explain to the SEC staff why such revisions or supplemental information are not necessary. Some of the comments included in the sample letter relate to:

- discrepancies in the level of climate-related disclosure in the issuer's ESG Report as compared to its SEC filings
- material effects of transition risks related to climate change
- regulatory changes and the impact on the issuer's business, including indirect effects
- material past or future capital expenditures for climate-related projects
- physical effects of climate change on the issuer's operations and results
- compliance costs relating to climate change and
- purchase or sale of carbon credits or offsets.

This sample letter helps to clarify for issuers the SEC's areas of focus for climate-related disclosures by emphasizing the points that were originally raised in the February 2010 interpretive guidance and drilling down on the specific types and level of disclosure the SEC staff expects to see in future filings. While the SEC had been issuing similar types of comments in prior comment letters, the sample letter helped to focus attention on this topic by including the various types of comments in one place for reference. If the SEC continues to provide similar guidance in other areas under the ESG umbrella, such as measuring carbon neutrality, or supporting equality in the workforce, companies and their investors will have the benefit of an increasingly clear roadmap for preparing their disclosures, including insight as to the type and depth of coverage expected by the SEC.

In March 2022, the SEC proposed landmark rules mandating disclosures regarding climate change and climate-related risks. These proposed rules received in excess of 14,000 comment letters and are arguably one of the most important proposed SEC rules in a decade. While some comment letters were supportive, many, particularly those from industry groups like the

Society for Corporate Governance and the Council for Institutional Investors, argued that the SEC should scale back some of the rule's more burdensome, ill-defined and prescriptive requirements. For example, many business decisions, such as a decision to purchase a fleet of electric, hybrid or gas vehicles, are made for multiple reasons, and it is unclear how companies will categorize whether such purchases constitute climate-related expenses. We expect to see final rules in 2023, and the proposed implementation timeline included in the proposed rules indicates that the SEC will expect issuers, especially Large Accelerate Filers, to implement the rules quickly rather than providing for a considerable transition period.

Coupled with these increased disclosure requirements, it is expected that the SEC will also increase its level of examinations and enforcement in this area. The creation of the Climate and ESG Task Force within the SEC's Division of Enforcement (and led by the Acting Deputy Director of Enforcement) in March 2021 suggests that the SEC intends to ramp up enforcement of ESG-related violations. As noted in the SEC's press release announcing this new initiative, the task force will develop initiatives to proactively identify ESG-related misconduct and "coordinate the effective use of Division resources, including through the use of sophisticated data analysis to mine and assess information across registrants, to identify potential violations."

Additionally, in a Risk Alert issued in April 2021 entitled "Division of Examinations' Review of ESG Investing," the SEC highlighted observations from recent examinations by the SEC of investment advisers, registered investment companies and private funds offering ESG products and services. It encouraged market participants that promote ESG investing to clients to:

- evaluate whether their disclosures, marketing claims, and other public statements related to ESG investing are accurate and consistent with internal firm practices;
- ensure that their approaches to ESG investing are implemented consistently throughout the firm, adequately addressed in the firm's policies and procedures and subject to appropriate oversight by compliance personnel; and
- document and maintain records relating to important stages of the ESG investing process.

Again, this type of feedback seems to be meant to put investment advisers on alert that more scrutiny of their practices, including possible additional enforcement actions, are likely to come.

Market participants should stay tuned for more developments in this area, in particular, developments related to the SEC's climate disclosure rulemaking.

F. Environmental Justice

Brooke Goodlett and Joanna Kass

Environmental justice describes the relationship between climate change and human rights. According to the US Environmental Protection Agency, environmental justice is "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." Environmental justice is closely linked with diversity, equity, and inclusion, which are cornerstones of the "S" in ESG.

On September 8, 2022 ruling, the Louisiana District Court addressed an issue of environmental justice in *RISE St. James et al. v. Louisiana Department of Environmental Quality (LDEQ)*. In this case, the court ruled that LDEQ violated its duty as a public trustee by failing to conduct a fair and rational analysis of the environmental costs to the community. LDEQ had granted permits to a plastics company to construct a large chemical complex adjacent to a community called Welcome with a 99% minority population, and the court vacated these permits. The court stated that LDEQ was obligated to conduct an environmental justice analysis as part of its public trustee duty.

Shareholder activists have also taken a stance on environmental justice, including one activist that evaluates environmental justice as part of its Racial Justice Scorecard. On this scorecard, a large American pharmacy ranked in the top 10 of companies due to its health zone initiative that has improved minority access to healthcare. Stakeholders are gaining interest in environmental justice, and both life sciences companies and the communities that they serve will likely benefit from incorporating environmental justice into business strategies.

G. Climate Commodities

Deanna R. Reitman

As technologies are developed to perform current tasks in a manner that produces less carbon (CO₂), there are opportunities to generate carbon offset credits from such emerging technologies. The mechanism for generating carbon credits that have actual, tradable marketable value, is to have these new technologies "verified" or "certified."

The carbon credit verification or certification methodologies (Methodologies or Methodology) are detailed procedures for quantifying the real GHG benefits of a technology. The registries that create these Methodologies provide guidance to help technology developers determine technology boundaries, set baselines, assess additionality (explained below), and ultimately quantify the GHG emissions that were reduced or removed.

The two most popular methodologies are for VERRA and Gold Standard carbon credits.

VERRA

Methodologies

VERRA has multiple categories of Methodologies already developed and ready for use. However, if a current methodology does not fit the technology, technology developers can choose to develop their own methodology through the VCS methodology approval process (MAP). Under MAP, proposed methodologies are reviewed by VERRA, and assessed and validated by an approved validation/verification body (VVB).

The basic steps of the MAP, include:

- Methodology developer prepares and submits a methodology concept note
- VERRA reviews methodology concept and accepts it into the full MAP, if it meets evaluation criteria
- After the concept note is accepted by VERRA, the methodology developer prepares and submits documentation
- VERRA reviews methodology
- VERRA conducts 30-day public consultation
- VERRA contacts VVB to assess the methodology and produce an assessment report, and methodology developer pays VVB directly



- VERRA reviews documentation and assessment report and
- VERRA approves methodology for use if it meets all VCS Program requirements.

Gold Standard

Gold Standard was founded by the World Wildlife Fund and other NGOs to serve as the benchmark in carbon markets. This standard sets requirements for technology design with a goal of maximizing positive impacts on the climate and to measure and report such impacts in the most credible and efficient way. Gold Standard customizes safeguards, requirements and methodologies to measure and certify activities that impact climate protection.

A Gold Standard certified technology must meet certain requirements to be certified within the program. These technologies have to generate carbon credits which represent the reduction or removal of one ton of CO₂ equivalent.

Gold Standard technology driven projects can result in the creation of Gold Standard Verified Emission Reductions (VERs) for voluntary climate action and Certified Emission Reductions (CERs) for meeting compliance targets.

VI. Integrating ESG into Business Decisions

A. Supply Chain Management

UTGSLI, Lauren Murdza and Brooke Goodlett

Sustainability standards in the supply chain are paramount to the long-term success of the life science sector. Due to the unexpected nature of the COVID-19 pandemic, lockdowns severely impacted economies and markets around the world, effectively exposing the vulnerabilities of supply chains. The pandemic presented a new set of risks affecting supply chains, such as decreased labor availability, governmental mandates, and an inability to travel globally in some cases. Global economic and geopolitical instability has continued to cause disruptions within supply chains in every sector. However, the life sciences sector has been particularly vulnerable to supply chain fragilities due to the globalization of supply chains in the sector. For example, active pharmaceutical ingredients (APIs) are often imported from other countries, and life sciences companies realized the need to seek out secondary, and even tertiary, suppliers in the case of shortages, price spikes, and manufacturing delays during COVID-19. The pandemic also exposed the importance of adopting new technologies to provide increased supply chain visibility, better labor conditions concerning the health and safety of employees, and contingency plans across the supply chain. Innovations in supply delivery technologies were paramount during the COVID-19 pandemic to address global distribution of product.

While the pandemic caused many negative impacts on supply chains, it acted as a catalyst for the much-needed change to supply chain management. By exposing supply chain risks and vulnerabilities, the pandemic made it clear that proactive planning, communication, and adaptability within supply chains are necessary. Life sciences companies have used several strategies to address supply chain issues, such as drafting contracts that include language for price renegotiations, allocation penalties, and step-in rights to obtain secondary suppliers. There has also been a trend towards conducting supply chain gap analysis for companies to determine whether they have the necessary resources to meet their production and output goals. It is best if companies and suppliers are collaborative in contract renegotiations, as well as in conducting advanced

forecasts to mitigate risk and manage any potential shortages of raw materials. Being proactive in supply chain management planning is critical as each supplier will be subject to regulatory inspections specific for its role in the supply chain.

Due to the complexity and global nature of life sciences supply chains, corporations should analyze their downstream and upstream stakeholders to ensure complete compliance to legal, ethical, and ESG standards. From a social ESG standpoint, one initiative that many pharmaceutical companies adhere to is the PSCI Principles for Responsible Supply Chain Management (the "Principles"), which outline ethical human rights, labor, and health and safety standards for workers in a global life sciences supply chain. These Principles have encouraged life sciences companies to reduce their dependence on foreign suppliers who often employ marginalized, low-skill workers and may commit human rights violations. For instance, in the pharmaceutical industry specifically, 80-90% of the preliminary phase of pharmaceuticals are conducted overseas and have gained attention from the FDA due to poor worker health and safety practices and instances of coerced labor. The PSCI Principles ensure that corporations protect workers from biohazards, inhibit the utilization of child laborers (children under the age of 18), and pay a fair wage. Globally, the Principles also work towards worker diversity and inclusion by eliminating discrimination based on religion, gender, sexuality, age, pregnancy, or other characteristics, with clauses in place addressing physical and mental harassment. Efforts to maintain transactional accountability include an emphasis on anti-bribery and corruption to regulate fair trade.

From an environmental perspective, pervasive issues exist in life sciences sector supply chains, such as the waste and disposal of unused medicines, unnecessary packaging and leafleting in medicine provision, and the carbon footprint of large-scale medicines manufacturing. Life sciences companies can set targets to reduce direct and indirect greenhouse gas

From an environmental perspective, pervasive issues exist in life sciences sector supply chains, such as the waste and disposal of unused medicines, unnecessary packaging and leafleting in medicine provision, and the carbon footprint of large-scale medicines manufacturing.

emissions, as well as “value-chain emissions,” so as to reach the “net-zero” goal set up by the Paris Agreement. Efforts include right-sizing business, improving energy efficiency, using renewable energy sources, and offsetting unavoidable emissions via carbon sequestration projects. Efforts to “green up” the industry also include new models for biodiversity risk management and biodiversity assessment in the supply chain. Benefit sharing packages that include a wide range of monetary and non-monetary benefits over time have become standard practice. Strategies are also designed to protect forests and support farmers and indigenous communities in integrating biodiversity conservation and climate adaptation into crop production.

Supply chains in the life sciences sector are further complicated by the great number of stakeholders. For small molecules, this includes the API provider, the drug manufacturer, packaging and distribution companies, regulators, hospitals, pharmacies, health-care providers and patients. For biologics, the supply chain becomes even more complicated and cumbersome before taking into account second, or third, sources for each supplier. Without robust due diligence, pharmaceuticals may find themselves exposed to greater risks, which might be heightened by the high volume of M&A in the sector and the built-in data and regulatory exclusivity periods and patent expiration periods. Digital technologies could help, especially when life science companies have a complex, fragile, and extended supply chain. Accessible data, AI-empowered due diligence and digital solutions, and new technologies such as blockchain could be crucial in driving the change. Companies should also strongly consider seeking independent third-party audits of their value chain providers. There is no one-size fits-all solution to supply chain management, and life science companies should consider their unique product offerings and production needs to develop a comprehensive strategy.





B. Real Estate

Mike Bedke

The life sciences sector's growing real estate footprint, both within the US and abroad, means a growing role for counsel. It also implicates a wide array of ESG issues, such as the labor and procurement practices of contractors and other partners, compliance with safety and other regulations, evolving environmental risks, waste generation and disposal, energy use and efficiency, and even the cultural significance of a given built site to its original inhabitants and their ancestors.

The life sciences sector has a growing real estate footprint, both within the United States and elsewhere. This tremendous growth implicates a wide array of ESG issues. Environmental risks such as flooding, hurricanes, wildfires and other weather-related events are fairly obvious. Energy use and efficiency is also becoming a major issue for the sector. Research labs and their impact on communities, in part due to safety and security concerns whether real or imagined may garner increased scrutiny.

Construction and Procurement: Whether building a life sciences campus from scratch or setting up in an existing facility high-rise, a life sciences company's real estate choices are an important part of its brand and operations. Protecting both requires sound ESG practices. And with so many moving parts and legal needs, constructing and procuring commercial real estate can present companies with many critical ESG decisions. Companies should seek to ensure that their contractors, subcontractors, and suppliers are aligned with the company's ESG policies. This is often achieved with clear and conspicuous codes of conduct, contractual provisions that enforce adherence to corporate ESG standards, and robust auditing mechanisms for verifying compliance.

Other issues of cultural significance are increasingly arising in new development projects. Whether it is ancient burial grounds of indigenous people or forgotten cemeteries of displaced and underserved communities, there is new sensitivity to investigating

While LEED pertains to a building's impact on the environment, WELL and Fitwel pertain to a building's impact on the health and well-being of the people who occupy the building.

the history of sites being considered for new development. Major projects in the heart of metropolitan areas have been canceled or delayed due to the discovery of such sacred and culturally sensitive locations. Counsel should not infer projects in urban areas or brownfields are exempt from these potential issues. Just as one investigates environmental impacts on protected and endangered species, one should look into the history of a development site.

Branding is, obviously, extremely important to companies, particularly so to those in the life sciences sector. Competition for talent and customers is mission critical to those in the life sciences sector. A company's real estate portfolio, whether leased or owned, is an increasingly important aspect of branding and the recruitment and retention of employees. A company's real estate decisions may even impact the productivity of its people. As a result, corporate users and life sciences sector clients and customers are likely to look to properties that are not just LEED (or Green Globes or ENERGY STAR) certified but also to those that are WELL or Fitwel Certified. While LEED pertains to a building's impact on the environment, WELL and Fitwel pertain to a building's impact on the health and well-being of the people who occupy the building. The focus is on the quality of light, water, air, nourishment, fitness and the like. These buildings shape health and well-being for "good health and good business." It should be noted that numerous studies by Michigan State University, the University of San Diego and UCLA found such buildings resulted in increased productivity among the workers occupying the space. Counsel should consider how these certifications impact leases, covenants, conditions and restrictions and the like in the context of the monitoring of, adherence to, and compliance with such standards. By way of example, what if a breach results in the loss of tax credits?

As evidenced by WELL and Fitwel, socially responsible decisions no longer just focus on environmental issues. Increasingly, adaptive reuse not only helps with green and sustainable building (as it often lowers the carbon footprint of a project) but also may revitalize

an area. One example is the Crosstown Concourse project in Memphis, Tennessee that transformed an abandoned warehouse into a vertical mixed-use village including healthcare services, performing arts theatres, retail, residential, educational and office opportunities. It resulted in the revitalization of an underserved community.

Environmental Sustainability: Leading the state of the art is often key to life sciences sector branding. Today, sustainability is state of the art. New and retrofitted construction will contribute to a company's environmental impact, including its GHG emissions, energy and water consumption, and waste. Policies requiring certain efficiency standards in new real estate and the adoption of "green lease" provisions can help mitigate environmental impacts and even turn a company from a net consumer of power to a net producer.

The green real estate movement is not simply a fad. The life sciences sector may maximize benefits of owning and leasing green assets. Increasingly, federal, state and local governments and regulators are weighing-in and mandating certain standards in connection with the development, construction, and operation of properties. There is often a carrot and stick approach--these may include penalties for non-compliance and incentives (increased density, tax credits/abatements, expedited permitting, PACE financing, green bonds) for "going green." REALpac, BOMA, Corporate Realty and Managements and others have form green leases and lease provisions. Thought should be given to how standard provisions (such as a permitted use clause in a lease) should be revised to protect the company's sustainability requirements, environmental management plan, financing covenants, commitments to stakeholders and the like. Also, consider that data sharing is often important as parties share information on building materials, cleaning products, energy use, water consumption and other factors. Robust data and tracking of assets, such as by using special software to benchmark and identify opportunities, can result in value creation for the company.

C. Cybersecurity and Data Security

UTGSLI and Angeline Chen

I. CYBERSECURITY GOVERNANCE AND INVESTMENTS AS AN ESG METRIC

Cybersecurity should be seen as a fundamental component of every ESG program. The criticality of securing the systems, networks, programs, and the data residing on those systems upon which businesses and their partners rely, span across all three of the ESG pillars in different yet interdependent ways.

A cyberattack can cripple an organization's information infrastructure and systems, rendering data inaccessible, unreliable or lost and used in an exploitation attempt. Vulnerabilities can be found and exploited at multiple points throughout the business, including from even insiders. Cybersecurity thus presents one of the most critical sustainability risks to organizations today. In a digital economy, every entity is a target of opportunity for hackers with a range of motives and easily accessible tools and exploits. Successful attacks result in material business disruption, loss of proprietary data and trade secrets, financial instability, erosion of customer trust, and reputational damage. In short, cybersecurity risk touches each and all parts of an organization. The impact of cyberattacks and breaches pose a threat to

the social and environmental pillars of ESG, while the entity's security posture, management of cybersecurity investments, and recovery protocols must be integrated into the governance pillar of ESG.

In addition to disrupting the community and social life of stakeholders, data loss or compromise can be devastating to company valuations and extremely difficult if not impossible to recover through insurance. Building a more resilient cyber infrastructure and enhancing cybersecurity risk management skills will drive corporate growth. Life sciences organizations need to balance technology innovation and individual privacy rights when they are collecting and consuming more protected health information (PHI) with the development of telehealth and wearable medical devices. In addition to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), new regulations are called for to accommodate a decentralized approach to care.

The healthcare industry held the highest average data breach cost of any industry for the 12th year in a row.



In 2021, the adjusted average total cost of a data breach reached \$4.24 million per company, a 10% rise from the prior year. For the healthcare industry, the cost of a breach went up 42% from 2020 for an average cost of \$10.10 million. The healthcare industry held the highest average data breach cost of any industry for the 12th year in a row. The onset of the pandemic saw an exponential increase in vulnerabilities associated with a remote workforce and often decentralized, sometimes ad hoc, systems and devices stretched beyond their original IT architectural design. INTERPOL noted not only a significant increase in cybercrime, but likewise a material shift in targets from individuals and small businesses to major corporations, critical infrastructure, and governments. Investors and regulators are taking note. In March 2022, the Securities and Exchange Commission proposed new rules related to cybersecurity disclosure and governance. If adopted as proposed, public companies will be required to be more transparent, and enhance and standardize their disclosures regarding their cybersecurity risk management, strategy, governance, and incident reporting. As companies increase the attention paid to their cybersecurity practices, viewing cybersecurity and data protection from an ESG lens may provide a company with additional value-add market opportunities and build trust with its customers and other stakeholders.

II. CONCEPT OF “FUNDAMENTAL HUMAN RIGHTS” AND DATA PRIVACY

Jurisdictions around the world hold differing views regarding privacy and associated data protection surrounding individuals. For example, the European Charter of Fundamental Rights upholds ideals such as human dignity, freedom, equality, and solidarity. Privacy, or the right to a private life, to be autonomous, to control information about oneself, to be left alone, is essential to human dignity. However, data privacy is not an absolute right and is often balanced against other human rights, public or private interests. The General Data Protection Regulation (GDPR) came into effect in 2018 to harmonize privacy and data protection laws across Europe. This comprehensive legislation set up clear corporate compliance standards on transparency and obtaining informed consent of users. Other countries and regions in some instances adopt a similar perspective and national laws, while others weigh the government’s or a third party’s right to access, keep, and use such data more heavily. Some countries, including

the United States, do not recognize privacy as a fundamental human right and instead promulgate laws that focus on the types of data and purposes for which such information about an individual might be shared, resulting in a “patchwork” of laws and regulations governing data protection and privacy.

In both the US and Europe, the “right to be forgotten” is a notion that details that an individual has an authority over their personal data that may be controlled or in possession by another organization. Specifically, the GDPR’s definition of the “right to be forgotten” ensures that an individual can request that all personal data be removed or deleted when the explicit terms of the data collection process no longer apply. In the healthcare industry, the proliferation of health, genetic, and biometric data has invoked momentum towards finding a balance between innovation and health care data privacy.

III. ZERO TRUST SECURITY, SECURE BY DESIGN AND INFORMATION SECURITY STANDARDS

Adopting cybersecurity frameworks and following information security standards will assist organizations in both incorporating cybersecurity into ESG strategies and infrastructure. Zero Trust is a security framework that requires all members of an organization to be authenticated and repeatedly authorized through verification processes. This method is created to align with remote, hybrid, and traditional styles of working to address modern security challenges including ransomware threats or large-scale hacks. Secure by Design is a security initiative through which engineers develop the infrastructure with security built into every part of the IT management process from the beginning of production instead of conducting patchwork after the product is finished or displaying vulnerabilities. ISO/IEC 27001 provides a recognized international standard for the adoption of cybersecurity best practices and security controls. In the United States, multiple information security standards issued by the US National Institute for Standards and Technology, such as NIST 800-207 and NIST SP 800-171, likewise address specific types of systems and industry sectors. Other tools and models are becoming more established and recognized as means of demonstrating a stronger cybersecurity risk profile. Given the types of data and business activities engaged in by entities in the life sciences sector, a thoughtful evaluation and adoption of cybersecurity best practices and security controls should be seen as an ESG mandate, not an option.

D. Building a Resilient Business in a Post-Pandemic World

UTGSLI and Brooke Goodlett

The resilience of the life sciences sector has emerged as a major issue in the wake of the past three years of global instability and uncertainty. The development of the COVID-19 vaccine demonstrated the power of the life sciences sector to persevere during a crisis and save lives. The speed at which the vaccine was developed was remarkable and was a best-in-class example of an industry working together to improvise, adapt and overcome. At the same time, the COVID-19 pandemic has exposed many vulnerabilities in our economy, and in our life sciences and healthcare system. Working toward resilience, ESG issues need to be considered as we work our way toward recovery and improvement for our environment. This pandemic has opened the pathway for many companies, life sciences or corporate, to discover other ways of doing work and keeping the economy going whilst warding off a virus. These adaptations of telehealth, virtual reality, and hybrid events have introduced a way for companies to advance healthcare and society in a more effective and sustainable way. This is happening through adopting new strategies for innovative trials to shorten timelines, using new technologies to better relay research and findings, and developing influential and strategic partnerships. Technological advancements such as virtual clinical trials have been able to provide much greater patient involvement and improve diversity and ultimately attain most relevant and constructive findings.

Corporate resiliency is broadly defined as an ability to tolerate stress, maintain functionality, and seek new opportunities as they arise. The COVID-19 pandemic has particularly underscored the need for companies to develop strong organizational and business resiliency amidst an ever-changing and globalized world. Life sciences companies often face substantial resiliency issues. Supply chains in the life sciences sector are mostly located abroad, with a significant dependence on China, which holds over 70% of the world's active pharmaceutical ingredients.

Even three years later, the COVID-19 pandemic continues to cause significant disruptions, as well as new opportunities, in the life sciences sector.

Undoubtedly, the unexpected nature of this pandemic severely impacted economies and markets around the world. Businesses across the country and around the world experienced supply chains interruptions, precipitous decline in demand for their products and services, shortages in supplies, and government-mandated closures. While life sciences companies have worked tirelessly to develop vaccines and treatments for COVID-19, the pandemic also significantly impacted research and development progress for new medical advancements. For example, the initial lockdown beginning in March 2020 caused more than 50 percent of companies to temporarily pause recruitment for the majority of trials.

The severe disruptions caused by the COVID-19 pandemic continue to reverberate today and contain essential lessons for the life sciences sector in navigating the future. Companies should implement and frequently review crisis management and contingency plans for pandemics and other disruptive risks and plan accordingly. Such strategies will likely emphasize collaboration with the public sector and health officials as necessary to remain responsive to new threats. Additionally, companies should adopt a flexible mindset in adapting to changing customer demands for new services and products, as well as the needs and demands of their workforce, such as establishing flexible teleworking arrangement for employees.

The solutions for bolstering resilience of the life sciences sector are multi-faceted. Companies should embrace the principles of redundancy, diversity, and adaptability to establish a long-lasting corporate structure. In practice, this means that a resilient company should consider replicating elements of its business to ensure back-up plans for any potential point of failure (redundancy); utilizing different standards of operation when prudent and seeking people of diverse backgrounds (diversity); and acclimating to new situations with a flexible and purposeful mindset (adaptability). Life sciences companies in particular should consider increased transparency in the traditionally opaque

pharmaceutical supply chain process and greater incorporation of digital health care delivery models. Additionally, boards and management should review crisis management and contingency plans on a regular basis to ensure that the company is prepared for looming threats. Incorporating these principles would allow a company to anticipate threats faster, better resist the initial shock and respond accordingly. As the life sciences sector wrestles with increasing geopolitical, environmental, and social changes, resiliency remains the key bulwark for any company to thrive and compete in the global business market.

Companies should implement and frequently review crisis management and contingency plans for pandemics and other disruptive risks and plan accordingly.



VII. ESG Risks

A. Truth in Advertising

Heather Dunn, Carissa Bouwer, and Jordan Chisek

As consumer awareness of environmental issues increases, more brands are using eco-friendly aspects of their products or business to differentiate themselves in the marketplace. However, it is important that brands tout the benefits of their products and services in a manner that is not deceptive or misleading to avoid false advertising and unfair business practice claims from competitors, consumers, and state and federal regulators, such as the Federal Trade Commission (FTC).

In October 2012, the FTC issued updated guidelines for advertising claims related to “green” products and services (FTC Green Guides). The FTC Green Guides encourage marketers to avoid deceptive or misleading claims by making disclosures in plain language and using sufficiently large type. Marketers should not make claims unless all reasonable interpretations can be substantiated. Since it is incredibly difficult to substantiate all interpretations of unqualified general environmental benefit claims that have broad meanings, such as “eco-friendly,” the FTC Green Guides suggests avoiding them entirely. The FTC also provides guidance on claims related to certain subjects, such as carbon offsets, certifications and seals of approval, degradable claims, free-of claims, non-toxic claims, and claims that products are recyclable or made from recycled content, as well as claims regarding use of renewable energy and renewable materials. For example, the FTC Green Guides advise that in addition to having reliable scientific evidence which supports carbon offset claims, marketers should disclose if the carbon offsets will not occur within the next two years, and they should refrain from making the claim at all if the carbon offset activity is already required by law. Companies must also be careful about making aspirational statements about sustainability goals they have not yet achieved.

When making claims, marketers should not rely on statements made by vendors or suppliers. Before repeating a claim, it is important to understand how the

claimant is substantiating the claims. If a company is asked to substantiate an environmental claim, reliance on a third-party statement alone would not suffice as substantiation.

States are also increasingly targeting sustainability claims. California, Washington, Wisconsin, Indiana, Minnesota, and Florida have all passed laws related to environmental claims such as “environmental choice,” “recyclable,” “compostable” and “ozone friendly” and more states are considering similar laws. Cal. B&P § 17580; Wis. Stat. Ann. § 100.295; Ind. Code § 24-5-17-2; Mich. Comp. Laws § 445.903; Minn. Stat. Ann. § 325E.41; Fla. Stat. Ann. § 403.7193.

Companies should be aware when selecting company and product names, that names and trademarks themselves can convey environmental messages. For example, use of “Green” or “Eco” in a product name may be considered an environmental claim. Companies should consider the FTC Green Guides and state laws during the trademark selection and clearance process.

Deceptive environmental claims can lead to enforcement actions by regulators such as the FTC and state Attorneys General and can lead to consumer and competitor claims in court or with the National Advertising Division of the Better Business Bureau, as well as consumer class action lawsuits.

B. Disputes

Noah Schottenstein

ESG disputes can arise under a variety of legal theories and with a variety of plaintiffs. These include, among other theories (i) securities disputes based on allegations of misstatements and omissions in connection with prior ESG representations to investors; (ii) consumer protection and unfair competition disputes in connection with allegations of misrepresentations made to

The FTC Green Guides encourage marketers to avoid deceptive or misleading claims

consumers; (iii) tort disputes related to harms caused by company products or third-party contract counterparties such as customers, suppliers, or other strategic partners; and (iv) breach of fiduciary cases brought by states, stockholders or other stakeholders that a company has not gone far enough, or has gone too far, in pursuing a particular ESG goal. To date, private-parties — most prominently public interest groups — have been responsible for driving ESG disputes. But government agencies have been demonstrating greater interest in ESG-related corporate accountability across the board. Life sciences companies are already subject to heightened regulatory scrutiny and are therefore more likely to draw attention with respect to ESG practices. And government plaintiffs have access to far greater investigatory powers and remedies than the typical private-party plaintiff, which significantly increases the risks associated with a government dispute.

Strategies for resolving ESG disputes are largely dependent on the nature of the dispute and the type of plaintiff that the company faces. It is therefore critical for companies to retain litigators who understand the different perspectives and interests that motivate a particular dispute. Doing so will allow companies to consider a dispute as an opportunity to engage with and learn from stakeholders. Approaching all disputes with the same strategy will prevent companies from developing creative solutions and taking advantage of the unique opportunities that a litigation settlement can provide.

C. Class Action Risks

Keara Gordon and Isabelle Ord

Class action risk arising from ESG policies and practices is an emerging threat that will ultimately encompass all three pillars of ESG. Some early examples of ESG class actions arose under the environmental pillar, such as lawsuits seeking to hold oil companies responsible for the costs and effects of climate change as well as “greenwashing” complaints involving allegations that a company has generally made false or misleading claims about ESG compliance. While there have

been some challenges to date, as more and more companies develop and implement their ESG approach and regulators pay closer attention, securities litigation and related enforcement actions challenging the veracity of ESG representations will proliferate. While many have perceived these risks as primarily acute for public companies, they are not so confined, as these issues also trigger issues of corporate governance.

We are seeing an increasing number of consumer fraud putative class actions challenging ESG statements, such as 100% recyclable, or “dolphin safe,” or similar. Ultimately, consumer protection statutes involving false advertising and unfair business practices may provide a framework for class actions predicated on conduct under any of the three ESG pillars. Indeed, existing class action trends such as challenging whether a product is organic or manufactured according to a business’s “green” ethos can be considered ESG class actions.

A broad variety of ESG class actions have begun or are coming, including matters related to fair or ethical labor practices in supply chains, diversity and inclusion goals, representations regarding a company’s commitment to specific practices, and statements or actions regarding “cancellation” of disfavored businesses. Potential exposure in these types of class actions could be significant and may also attract regulatory attention. Now that the European Union’s Collective Redress Directive is in the course of implementation and the UK is establishing a framework for more-US style class actions, companies may increasingly face coordinated class actions and regulatory proceedings targeting ESG related conduct in both the US and other jurisdictions globally.

Companies can seek to mitigate their ESG class action risk by vetting their ESG policies and practices, reviewing the wording of public commitments carefully, potentially considering appropriate disclaimers, ensuring accuracy of regulatory disclosures and advertising, and integrating ESG compliance into corporate governance priorities.

D. Anti-Energy Boycott Laws

Brooke Goodlett and Victoria McGuire

While the financial services industry has been the primary target of recent “anti-energy boycott,” also known as “anti-ESG,” lawmaking and activism, life sciences and other companies that do business with federal or state governments, have also been impacted. Anti-energy boycott laws generally refer to the governments of states reliant on certain industries, like West Virginia and Texas, which are each reliant on the fossil fuels industry, (i) divesting their pension funds from, ceasing business with, or otherwise boycotting, funds, asset managers or companies that boycott fossil fuels, or (ii) prohibiting their state pension funds from considering ESG in investment decisions. It can also refer to laws refusing to do business with companies that engage in a wide array of other ESG practices, such as boycotting firearms or lumber companies or conducting divisive antibias workplace training. The “anti-ESG” movement is based on several theories:

- That, in the context of funds, as a fiduciary, investors have a duty to act in the best interest of their clients to maximize profitability, while acting impartially. By focusing on ESG initiatives, investors are prioritizing social objectives ahead of financial returns.
- That, as discussed in Section VII.E. (“Antitrust Concerns”), certain ESG initiatives, such as fossil fuel boycotts, violate antitrust law.
- That certain workplace training initiatives cross the line from promoting diversity, equity, inclusion and belonging to illegally discriminating against employees who are White and/or male. For example, during the Trump Administration, Executive Order 13950 banned the use of certain “divisive” workplace training that engaged in “race or sex stereotyping” or “race or sex scapegoating” by federal contractors. Seen by some as an attack on diversity, equity, inclusion and belonging initiatives, EO 13950 was subsequently repealed by the Biden administration. In EO 13950, the Trump administration cited divisive training materials used by laboratories with federal contracts – one stated that “colorblindness” and “meritocracy” were “actions of bias” and another, as part of a training session for non-minority male employees, stated that placing an emphasis on “rationality over emotionality” was characteristic of White males.

- That certain ESG practices are harmful to certain industries that are of utmost importance to the state economy or are harmful to national security.
- That the transition from carbon and fossil fuels to renewable energy sources may exacerbate existing global inflationary pressures, a phenomenon sometimes called “greenflation.”

While only six states currently boycott companies that boycott fossil fuels, similar laws have been introduced in over a dozen other states. Additionally, some states have opened investigations of financial services companies under existing fiduciary duty laws, without passing new legislation. Life sciences companies with government contracts with states with anti-energy boycott laws should be mindful of the representations the state requires in their contracts and understand that many of these laws are ambiguous.

For example, Texas SB 13 prohibits governmental entities from entering into contracts valued over \$100,000, unless the contracting company expressly represents that it does not and will not boycott energy companies during the term of the contract. It defines “boycott” as: *without an ordinary business purpose, refusing to deal with, terminating business activities with, or otherwise taking any action that is intended to penalize, inflict economic harm on, or limit commercial relations with a company because the company [is in the fossil fuel industry or does not commit to or pledge to meet any environmental standards beyond applicable federal and state law] or a company that does business with such a company.* This broad definition invites subjectivity in the implementation of the law. This definition could arguably be stretched to apply to such situations as a company deciding to purchase a fleet of electric vehicles instead of gas-powered vehicles in a given year. Such a decision may have multiple business rationales, including predictions about the future price of fossil fuels or carbon taxes, and it is unclear how the State of Texas determines if a strategy is based in sound business judgement or an intent to inflict economic harm on a particular industry. It is also unclear how far the state will enforce the requirement that a state contractor not do business with a company that boycotts the fossil fuel industry. SB 13 and other similar statutes require the state government to maintain a list of financial companies that boycott fossil fuels, but these lists are typically limited to the financial services sector,

and not companies with state government contracts, creating additional ambiguity for companies with government contracts.

In the world of ESG, life sciences companies must balance the interests of multiple stakeholders, as well as navigate a labyrinth of state, federal and global ESG regulations. As discussed in Section IV.F (“ESG Materiality and Tools for Navigating Differing Stakeholder Concerns”), life sciences companies can balance these interests by conducting a materiality assessment, competitive studies and peer group analysis, and using these tools to inform a clear ESG mission. Companies with key contracts with states that have adopted anti-energy boycott laws should not only understand how to comply with these laws, but consider reaching out to the state in connection with its materiality assessment and maintain a clear line of communication about the state’s expectations.

E. Antitrust Concerns

Paolo Morante

Like many other types of competitor collaborations, a company’s participation in ESG-related activities – such as trade associations, standard-setting organizations, or other collective ESG efforts – can violate antitrust and competition laws. As relevant here, these laws generally prohibit agreements or understandings between independent economic actors that unreasonably restrain competition. Certain types of agreements, such as price fixing, bid rigging, or customer or market allocation

Some lawmakers have expressed concerns about “ESG collusion” and “climate cartels

agreements, as well as some group boycotts, are unlawful per se, which means that mere participation in such an agreement violates the law. Other types of arrangements between competitors or other independent economic actors are unlawful only if it can be shown that they produce anticompetitive effects that substantially outweigh any procompetitive benefits. Antitrust violations can carry severe consequences, including criminal liability for companies and individuals, treble or punitive civil damages, the imposition of burdensome conditions on a company’s business, debarment from government contracts, and significant reputational damage.

Antitrust analysis can be complex – companies and their employees should always seek advice of counsel before engaging in conduct that could raise antitrust concerns. Some lawmakers have expressed concerns about “ESG collusion” and “climate cartels,” suggesting that collaborative work on ESG matters can become the conduit for unlawful collusion among different market participants. It is therefore important, when engaging in various ESG initiatives involving other market participants, to ensure that legitimate activities do not spill over into unlawful conduct. In the ESG context, antitrust risk may be particularly high in connection with the following types of situations:

- **Activities involving communications and/or coordination with other companies, especially competitors**, that could lead to:
 - Agreements or understandings between competitors to fix prices, rig bids, or allocate markets or
 - The exchange of competitively sensitive information among participants. Companies should never share competitively sensitive information with others (especially competitors) without prior review and approval by competent counsel.
- **Agreements or understandings with other companies that exclude or disadvantage certain parties from or in the market (sometimes known as group boycotts)**. This could include an agreement among two or more companies not to do business with a counterparty that does not comply with ESG principles, or to deal only with a particular set of “ethical suppliers.” Unilateral decisions by a single company not to do business with certain parties are generally not problematic, but an agreement among two or more businesses not to deal with particular counterparties could raise antitrust problems.
- **Any collaboration among competitors, including without limitation standard-setting efforts or joint purchasing agreements, could raise antitrust concerns**. Many such arrangements may also be permitted, depending on the circumstances and particular facts of each case.

Companies can manage these risks by training ESG teams on antitrust matters and ensuring that compliance teams and antitrust counsel approve any ESG-related partnerships or collaborations.

VIII. ESG Opportunities

A. ESG Finance

UTGSLI, Dr. Ehab Elsonbaty, Deanna Reitman and Erin Lachaal

I. GREEN BONDS

Green bonds are a specific type of bond—functionally the same as corporate and government bonds – designed for raising money for climate-related and environmental endeavors. Green bonds have grown in value and popularity tremendously since the early 2000s. Since the World Bank issued the first green bond in 2008, the green bond market share has reached an issuance valuation of \$269.5 billion in 2021. Major contributors to green bonds include a range of government and private organizations, with urban transport operators and sovereign nations topping the largest certified issuers. In addition, there are six major green bond funds run by major asset managers. Green bonds represent the changing landscape in capital markets, where investors are increasingly engaging with investments that have a positive and measurable impact on society.

These bonds have standards set by bodies such as the Climate Bond Standard Board (CBSB), which certify that green bonds will be funding environmental, sustainable, or climate-related projects. The CBSB utilizes a Certification Scheme that certifies projects aligning with the goals of the Paris Climate Agreement. The Certification Scheme has pre- and post-issuance requirements that must be met for initial certification and ongoing certification; other requirements include disclosure statements and performance indicators. [In the European Union, green bonds must adhere to taxonomy regulations.](#)

Green bonds include specific types of climate- and environmentally-focused bonds, such as Blue bonds—focused primarily on ocean and water-based projects—and climate bonds, which deal in climate-related projects endeavor to be certified as ‘green,’ but are not yet certified as ‘green’. A key factor to green bonds is their transparency and accountability, implementing standards set by climate experts designed to bring about positive impacts on the climate and environment. As of 2018, there were ninety-one eligible green bond projects with \$15.4 billion in commitments.

II. SUSTAINABILITY LINKED BONDS

Sustainability Linked Bonds (SLBs), are bonds with varying interest rates or other terms based on whether an issuer meets Sustainable Development Goal (SDG) objectives by a certain deadline. The objectives are measured by predefined Key Performance Indicators (KPIs) and predefined Sustainability Performance Targets (SPTs). This instrument is aimed to further encourage companies to contribute to sustainable developments and provide more issuers with access to the sustainable financing market. Unlike green bonds, the proceeds from SLBs are not earmarked for limited purposes, rather, they can be used to fund general corporate or other purposes.

In 2020, 84% of SLBs were issued in Europe, Middle East, and Africa, however, as of April 2021, those regions only account for 68% of total issuance, as SLBs see rapid growth in the Asia-Pacific and North America regions. SLBs also grew tenfold from \$11 billion in 2020 to \$110 billion in 2021.

The Sustainability Linked Bond Principles, or SLBPs, were established in June 2020 and provide guidance to companies in the form of recommendations of good market practices. They are designed to promote integrity and transparency in sustainable finance and are applicable to all types of issuers. The SLBPs **consist of five core components:**

1. Selection of KPIs
2. Calibration of SPTs
3. Bond characteristics
4. Reporting
5. Verification

III. UN PRINCIPLES FOR RESPONSIBLE INVESTMENT

The UN Principles for Responsible Investment (UN PRI), are a set of six principles for ESG-focused investors to follow when choosing where to invest. For investors focused on incorporating an ESG mindset into their investment portfolio, adhering to these six guidelines can help ensure long-term sustainability benefits for their investments. The six principles are as follows:

1. **“Principle 1: We will incorporate ESG issues into investment analysis and decision-making processes.**
2. **Principle 2: We will be active owners and incorporate ESG issues into our ownership policies and practices.**
3. **Principle 3: We will seek appropriate disclosure on ESG issues by the entities in which we invest.**
4. **Principle 4: We will promote acceptance and implementation of the Principles within the investment industry.**
5. **Principle 5: We will work together to enhance our effectiveness in implementing the Principles.**
6. **Principle 6: We will each report on our activities and progress towards implementing the Principles.”**

The UN PRI has disclosure requirements and an annual grading process on how an investor or asset manager is integrating ESG considerations into their funds and investment processes such as manager research, portfolio management, and proxy voting and engagement. UN PRI signatories must submit a transparency report about integrating ESG issues into their ownership and investment decisions. These findings are assessed by the UN PRI and are also publicly available. The UN PRI recently launched a stewardship initiative for institutional investors to engage with companies on human rights and social issues.

In 2005, then-UN Secretary-General Kofi Annan gathered a twenty-person investor group to develop the PRI. Since then, according to the UN, the group has grown to 5,166 signatories as of September 2022 representing over 90% of the total global assets under management. As asset managers and other investors commit to the UN PRI, they may integrate ESG principles into their investment analysis, increase engagement with the companies they invest in, and prioritize investments in companies that have robust ESG reporting and practices.

IV. ASSET MANAGER PRIORITIES

The priorities of asset managers have begun to shift as we emerge from the pandemic, with an increasing focus on investments that align with certain environmental, climate change and sustainability goals. The Intergovernmental Panel on Climate Change, (IPCC), made it strikingly clear in their latest report that immediate action must be taken in order to reach the goals of the Paris Agreement and to stop the world's temperature from rising past a point of irreparable harm. This alarming statement has led to many investors to expect companies to mitigate the environmental and climate transition risks to their company, especially the risks that effect their companies that stem from the negative impacts of climate change. As of 2019, 215 of the top global companies were facing \$1 trillion in climate change risks, and that staggering number is expected to rise further. These risks can include physical risks, such as floods destroying company property, or transition risks, such as the shifts in technology and innovation needed to stay competitive. As these risks become more prevalent, climate disclosure has become more vital as investors and market participants want to be able to make well-informed decisions that take into account this climate risk factor. The world's major asset managers have strongly advocated for the SEC's adoption of mandatory climate disclosure rules, citing a need for improved access to environmental risk, climate transition risk and such risks mitigation data in order to support the integration of analytics on such risks and risk mitigation actions into such asset managers' investment considerations.

Companies in all sectors have seen an increased interest in net zero commitments and decarbonization from asset managers who have formed groups, such as the Glasgow Financial Alliance for Net Zero (GFANZ) and the Net Zero Asset Managers initiative, devoted to achieving the goal of global net-zero carbon emissions by 2050. Several of the world's major asset managers are part of these groups, and each controls tens of trillions of dollars' worth of assets. Specifically for sovereign wealth funds, the One Planet Sovereign Wealth Funds (ONSWF) Framework guides and supports the integration of climate change risks in decision making, development of enhanced ESG strategies, and recommending TCFD as the universal standard for climate reporting. Specifically, at least 17 global asset managers have founded and/or joined the One Planet Asset Managers (OPAM) initiative to actively collaborate on the ONSWF Framework and

share research and expertise with the ONSWF members. The ONSWF network also includes 8 sovereign wealth funds and 8 private investment firms with over \$36 trillion in assets under management and ownership. About 58 % of Sovereign Wealth Funds are actively engaging with their portfolio companies on climate-related issues, and some are even moving to divest from companies on environmental grounds.

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Within the life sciences industry, drug pricing, access to medicine globally, environmental sustainability, and enhancing diversity in clinical trials have been identified as important ESG investing focuses, with “E” concerns often taking a backseat to these “S” concerns. However, the life sciences industry may begin to receive more pressure from asset managers, particularly those who are members of GFANZ or the Net Zero Asset Manager’s Initiative. The International Society for Pharmaceutical Engineering noted that a study conducted in 2019 found that the global pharmaceutical industry contributes 13% more carbon emissions than the car manufacturing industry. While asset managers consider peer group performance when making investment decisions, life sciences companies that proactively manage their environmental impact and carbon footprint may increase their access to capital and prepare for increased demands by investors and other stakeholders, including regulators and customers.

V. IMPACT FUNDS

As mentioned in Section II.C, “Why is ESG Important? Activism, Shareholder Proposals and Governance Engagement,” sustainable funds have exploded in recent years. The US Forum for Sustainable and Responsible Investment reports that the number of ESG funds has grown from 55 in 1995, to 1,002 in 2016, and to 1,741 in 2020, and that the value of the “US sustainable investment universe” has grown from \$639 billion in 1995 to \$17.1 trillion in 2021. This growth is expected to continue – a study by Morgan Stanley’s Institute for Sustainable Investing found that 95% of millennials surveyed were interested in sustainable investing.

One type of sustainable fund is an impact fund. Impact funds, or impact investing, focus on investments in business ventures which will have a positive and

The International Society for Pharmaceutical Engineering noted that a study conducted in 2019 found that the global pharmaceutical industry contributes 13% more carbon emissions than the car manufacturing industry.

measurable social and environmental impact while generating financial returns; they have a stated goal to seek to achieve a specific ESG benefit. Impact funds select companies for investment on the basis of the impact they seek to generate in society. Some examples of areas that impact funds have focused on include poverty reduction, construction of hospitals, education of girls, and in environmental areas such as reduction of emissions and carbon footprint. The World Bank Group’s International Finance Corporation estimates that \$2.3 billion were invested for impact generation in 2020, of which \$584 billion are privately managed and \$1.687 trillion are publicly managed.

Impact investing is characterized by a direct connection between values-based priorities and the use of investors’ capital. According to Professor Laura Starks of the University of Texas McCombs School of Business, impact investing involves ESG values—an approach in which the portfolio manager or client tries to make an impact by supplying capital. This is known as impact, or community

investing, which some people use to achieve impact goals. This category can also include engagement of firm management to change their products or behavior.

The assets under impact investing could be privately or publicly managed. The Impact Principles, launched in April 2019, provide a framework for investors to ensure that impact considerations are purposefully integrated throughout the investment life cycle.

While impact investing is a well-meaning trend that has increased in the post-COVID pandemic period, there are concerns that the tradeoffs involved in a preference-based system of investing may reduce financial returns. Studies show that the median impact fund realized a 6.4% return, compared to 7.4% from non-impact funds. Additionally, some states such as Texas have pursued “anti-ESG” investment policies and legislation. It is important to note, however, that money managers utilized impact investing as a way to manage risk in their portfolios and 86% of investors believe that incorporating ESG practices into investments can lead to better long-term returns.

The allocation of capital through impact funds presents an opportunity for the life sciences sector to positively influence our world. Data from the Centers for Disease Control and Prevention (CDC) shows that a majority of deaths are associated with social, environmental, and behavioral conditions. Impact funds with concentration in the life sciences sector have the potential to invest in companies developing cutting-edge devices to better

Major banks have launched biotech-focused impact funds, the largest of which is worth \$850 million.

diagnose and provide therapy to drive significant improvements to healthcare. Major banks have launched biotech-focused impact funds, the largest of which is worth \$850 million, and venture capital and private equity firms have allocated impact investing funds through the use of guiding principles like “research that drives innovation” and “breakthrough products.” These funds seek to address unmet needs of patients and create differentiated value in the life sciences sector.

VI. ESG CREDIT RATINGS

ESG credit ratings are distinct from the ESG ratings discussed in Section I.E (“ESG Reporting Frameworks and Ratings”). ESG credit ratings are based on ESG criteria and factors used by credit rating agencies, particularly, the “Big Three” major credit rating agencies: Fitch Group, S&P Global, and Moody’s. Standard & Poors describes ESG credit factors as factors that influence the creditworthiness of a rated entity, and which are visible enough to include in credit rating analyses. Some examples of these include climate transition risk factors, waste and pollution, social capital, risk management, and physical risk. Impacts of these factors may include changes in operating costs and requirements, profitability, cash flows, and risk planning. Climate transition risk – referring to a large-scale effort to reduce greenhouse gas emissions – and physical risk – referring to the impact of climate change on extreme weather events such as hurricanes and floods – have the greatest impact on credit ratings due to their increased relevance in policy making decisions.

For example, Fitch ratings (namely Sustainable Fitch’s ESG Entity Scores aka. ESG.ES) quantify the relative ESG efforts of corporations based on the leveraged finance issuer’s overall impact on environment and society. Fitch ratings consider analysis beyond data strategy to consider the major science-based taxonomies for environmental impact, UN sustainable development goals, governance profile of firms or group of firms (if economies of scale exists), the proposed European Union (EU) green bond standards, and International Capital Market Association (ICMA) principles, as well as sector-specific data.

According to Fitch Ratings in 2019, exposure to social impacts, customer welfare, labor relations, and government structure were the most important ESG elements that impacted credit ratings of US healthcare providers, pharmaceutical companies, and medical device manufacturers. In 2021, the University Hospital of Rennes in France had their credit ratings adjusted due to labor related spending pressure that resulted in employee strikes, but also higher salaries and increased public attractiveness of the hospital. This shows that ESG-related matters can impact the efficiency and profitability of organizations in the healthcare industry and are an important consideration for investment opportunities in such industry.

B. Emerging Breakthroughs in Life Sciences that Could Create a More Sustainable Future

UTGSI and Brooke Goodlett

As life sciences companies pursue ESG in their day-to-day operations and long-term planning, they should not lose sight of how the industry, as a whole, can create a more sustainable future for our planet. We conclude our Life Sciences ESG Handbook by highlighting some emerging breakthroughs in life sciences that could build a more sustainable future.

Super-Enzymes that Eat Plastics: *Ideonella sakaiensis* 201-F6, a new strain of bacteria, was found to be able to grow on PET and degrade the plastics in the process. Taken to an industrial scale, the microbial degradation of plastic could be a promising eco-friendly strategy to manage waste plastic materials.

Genome Editing for Biofortified Crops: Scientists use multi-role pleiotropic genes to enable plants to adapt to different environmental stresses at the same time. These biofortified crops could supply global food in a stable and sustainable way. Bolder practices use technologies such as CRISPR-Cas9 to insert entire genes or DNA sequences from other species to cultivate crops that are tastier, pest-resistant, and better adapted to a warming world.

Lost Genetic Diversity Rejected by Cloning: With a somatic cell and a reproductive egg from a common ancestor, scientists could fuse the two into an embryo that a surrogate will carry. By implanting the nucleus from the somatic cell to the egg, scientists create a fused cell that only contains the genes from the animal they are cloning and inject genetic diversity into the endangered population.

Eco-Friendly Nitrogen Fertilizer: Though nitrogen is critical to crop growth, nitrogen fertilizer has negative effects on the environment and climate. A more sustainable way is to use biological nitrogen fixation as fertilizer, which uses microbes to generate nitrogen from the atmosphere.

Global Antibiotic Resistance: Antibiotic resistance is one of the biggest threats to global health, food security, and development today. Scientists researched promising new drugs and tried to revitalize existing drugs, such as compounds that inhibit β -lactamase, compounds that inhibit cell-wall synthesis and compounds that prevent RNA polymerase from working.

Gene-Editing as a Medicine: In 2021, scientists infused a CRISPR therapy into the bloodstreams of patients to treat a genetic disease. Though CRISPR has been widely applied outside the body to correct genetic mutations, this is the first time that scientists have injected the technology into the human body to directly correct affected organs. In the future, this technology could be used as a medicine and revolutionize our world.

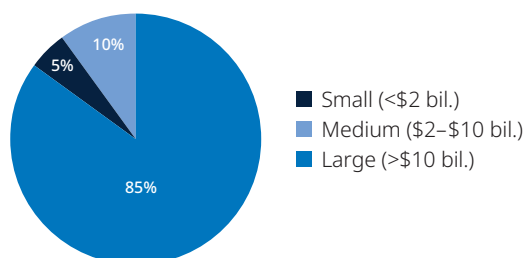
Digital Patient Access and Engagement: Virtual assistants, virtual care options, being able to sort or filter healthcare providers and make appointments online are considered highly helpful to patients, especially in times of the global pandemic. Multimodal patient access solutions are called for to meet diverse patient needs.

Price Transparency with Better Technology: When price transparency is being mandated for hospitals, new platform technology could provide patients with shoppable medical services. Seamless integration of medical and financial data can deliver pricing information to different stakeholders in real-time.

Appendix 1: About Our Datasets

Since 2019, DLA Piper's United States ESG Data Analytics team, based in Austin, Texas, has worked with our Life Sciences Sector to collect information on the sustainability disclosures and practices of life sciences companies to provide data-driven ESG information to our clients. Below follows a description of the datasets used in this report. Certain data collected over the course of this timeframe was excluded from our datasets as a result of mergers and acquisitions, "going private" transactions, outlier or other statistically insignificant variances or other factors that prevented us from tracking consistent ESG disclosures for the company over the applicable timeframe or challenged the reliability of the data. Our dataset includes data that is currently not publicly available, such as historical sustainability reports.

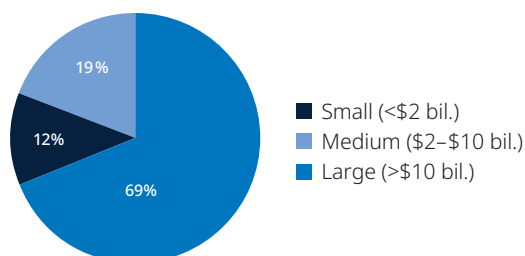
Market Cap 2021–2022



2021-2022 Dataset

From 2021 to 2022, we analyzed 40 life sciences companies that filed consecutive proxy statements with the SEC in these years. This dataset included 34 large market cap companies, 4 medium market cap companies, and 2 small market cap companies. The dataset included a variety of companies in the life sciences sector, including pharmaceutical, medtech and medical devices companies.

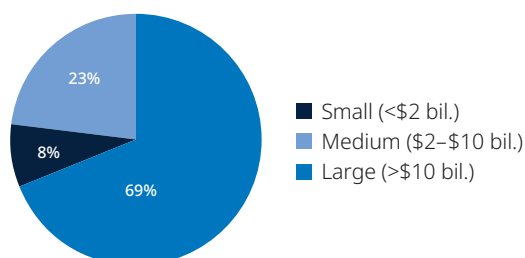
Market Cap 2020–2022



2020-2022 Dataset

From 2020 to 2022, we analyzed 16 life sciences companies that filed consecutive proxy statements with the SEC in these years. This data set included 11 large market cap companies, 3 medium market cap companies, and 2 small market cap companies. By 2022, 1 of the 3 medium cap companies grew to a large cap company. The dataset included a variety of companies in the life sciences sector, including pharmaceutical, medtech and medical devices companies.

Market Cap 2019–2022



2019-2022 Dataset

From 2019 to 2022, we analyzed 12 to 15 life sciences companies, depending on the particular issue at hand, that filed consecutive yearly proxy statements with the SEC in these years. This data set included 8 large market cap companies, 3 medium market cap companies, and 1 small market cap company. By 2022, 1 of the 3 medium cap companies analyzed grew to a large cap company. The dataset included a variety of companies in the life sciences sector, including pharmaceutical, medtech and medical devices companies.

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