June 17, 2022

Vanessa Countryman
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-0609

Re: File No. S7-10-22: The Enhancement and Standardization of Climate-Related Disclosures for Investors

Dear Secretary Countryman,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments to the Securities and Exchange Commission's (SEC or Commission) proposed rule to require information about a registrant's climate-related risks that are reasonably likely to have a material impact on its business, results of operations, or financial condition. The requirements would include disclosure of greenhouse gas emissions, forecasted impact of climate risks on financial metrics as part of audited financial statements, board oversight of climate risk, and management operational capabilities and responsibilities on climate risk assessment and management.[1]

BIO is the world's largest life sciences trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as managing the environmental and health risks of climate change, sustainably growing nutritious food, improving animal health, enabling manufacturing processes that reduce waste and minimize water use, reducing transportation emissions through the production of sustainable fuels, and advancing the health of our families.

The biotechnology industry is instrumental in advancing society and is considered a critical technology for American economic security in the new era.[2] Accordingly, we agree that climate change is one of the defining business risks of the 21st century. The rapid swings in climate and associated costs to businesses and economies have been increasing over time, and the biotechnology industry stands at the forefront of creating new solutions to these global problems.

[1] The Enhancement and Standardization of Climate-Related Disclosures for Investors
[2] https://www.whitehouse.gov/wp-content/uploads/2022/02/02-2022-Critical-and-Emerging-Technologies-List-Update.pdf

Biotechnology has the potential to be a transformative asset in the global race to bend the arc of climate change and offers new tools that can achieve at least three billion tons of CO_2-equivalent mitigation annually by 2030 using existing technologies.[3] Accordingly, BIO supports and shares the goal of addressing climate change, however, we are concerned that this proposal imposes significant burdens on registrants, especially small companies, without adding any benefit in addressing climate change.

The primary requirement underpinning the proposed rule is the disclosure of climate-related risks *reasonably likely to be material* to a business (model), business operations, or financial conditions. Yet, the Commission has determined that all registrants, regardless of size and sector and financial ability, should nevertheless take on potential additional costs, liabilities, reorganizations, and risks to comply with this policy. This comes as independent, international climate risk standards setting bodies, such as the International Sustainability Standards Board and the Science-based Targets Initiative, have found that climate risks are not material to the biotechnology industry[4] as well as several other industries.

BIO is concerned that potential negative effects will be disproportionately borne by small companies to the detriment of small business capital formation.

These regulations have real economic costs to all companies, particularly small biotechnology companies that have no product revenues but often fall outside of the scope of smaller reporting companies due to existing public float thresholds. BIO appreciates that the Commission proposes to exempt small companies from a portion of the reporting requirements (Scope 3), acknowledging that small companies will be disproportionately affected by the proposed rule while providing limited benefit to investors.[5] However the same could be said for the other proposed requirements, yet the Commission provides few exemptions or scale-up provisions to help small companies adapt to the current wave of public company regulation.

The Commission often cited comparisons to the S&P 500[6] and even the Russell 1000[7] as evidence that the market has already moved to report on climate and that the SEC must normalize these disclosures. However, the S&P 500 and the Russell 1000 are not accurate

[3] Biotech Solutions for Climate Report

[4] SASB Climate Risk Technical Bulletin 2021

[5] "…may pose fixed costs (e.g., data gathering and verification), that would fall disproportionately on SRCs. Also, **because SRCs are a small fraction of the market, the overall benefit to investors would be limited**."

[6] S&P 500 index analyses were cited repeated throughout the proposed rule.

[7] The Commission states that Russell 1000 companies "are virtually all large-accelerated filers" and further notes that "the rate of assurance is concentrated among the larger half of the sample firms (e.g., the S&P 500 firms)."

comparators for the status of small companies in the reporting of climate risk and greenhouse gas (GHG) emissions.

Finally, BIO urges the Commission and the Administration to take a holistic approach to their regulatory agenda with a particular focus on what this wave of regulation means for small companies, the diminishing incentives to become a public company they will create, and the potentially duplicative nature of reporting that will exist once the Administration's regulatory agenda is implemented in full.

Summary of Concerns and Recommendations

- BIO is **concerned** that the Commission is implementing a suite of new regulations that are not uniformly predicated on materiality and disproportionately harm small companies.

- BIO is **concerned** that the Commission continues to cite research and statistics about the behavior and risks associated with large companies and applying those models to small companies. The Commission relies on studies and statistics that apply to the S&P 500 and then uses that sample population to justify expensive regulations on small companies. Throughout this proposed rule, the Commission acknowledged both that most *large companies* are reporting and that small companies both do not report and would thus disproportionately be affected by implementation costs.

- BIO is **concerned** that the Commission is raising the cost of being a public company with no regard to the impact these regulations will have on small companies. BIO remains concerned that regulators are replicating past episodes of regulatory overreaction that led to distortions in capital markets with which the economy (across business owners, capital providers, and labor markets) are still contending.

- BIO **recommends** that Smaller Reporting Companies (SRC) be exempt from climate risk disclosures as the Commission has already acknowledged that "the overall benefit to investors would be limited[8]" in the case of the largest and most costly aspect (Scope 3).

- BIO **recommends** that the Commission update the definition of SRC to match investor definitions of small market capitalization companies by increasing the public float threshold to $2,000,000,000.

[8] Supra note 1

- BIO **recommends** that the Commission uphold the spirit of the JOBS Act by extending the EGC designation exemptions to climate risk disclosures, including the reporting and associated assurances.

- BIO **recommends** that the Commission extends safe harbors to all climate-related disclosures as many aspects of this proposed rule will involve third-party data, service providers, estimations, and forecasts. As the Commission noted, the calculation, assessment, methodology frameworks and assurances are "still evolving."

- BIO **recommends** that the Commission do not require Regulation S-X disclosures of climate-related impact estimates on consolidated financial statements.

Summary of Responses to Key Questions[9]

Climate Risk Materiality & Disclosure

BIO is concerned that the SEC is embarking on a path to redefine the standard of materiality.

BIO was drawn to the following line in the proposal, "…the **traditional concept of materiality** already requires the disclosure of climate-related impacts that materially affect the issuer's financial condition and results of operations,[10]" which was written in summarizing submitted comments contending that materiality standards already require companies to report on climate risks if they are material to a business. Troublingly, however, it appears that with this proposal, the Commission is intending to impose rigid across-the-board rules. As traditionally understood, a company makes independent assessments of what is material.

In particular, BIO is troubled that the Commission went so far as to define materiality in the context of financial-impact reporting by defining a one percent deviation attributed to climate related externalities as the threshold for reporting in consolidated financial statements. The Commission proposes a rigid reporting standard that is not rooted in individual assessments as dictated by the traditional concept of materiality. Furthermore, the one percent threshold for line-item reporting is too low to be considered material universally across companies and industries (as we explain in the Reporting Metrics Section).

[9] Please note that given the overlapping concerns across questions posed by the Commission in the proposal BIO has chosen to respond topically to those issues relevant to BIO membership and the biotechnology sector. This response does not include questions where BIO had no position. We have attached as an appendix the responses to questions, in-line.
[10] Supra note 1

While there are precedents for a one percent threshold, such as in the reporting of excise taxes in excess of one percent of total revenues, these are related to transactions that may be material to a business but are not attributed to exogenous, macro factors. This constitutes the first such instance.

Importantly, current guidelines and Commission guidance already contemplates that companies have a duty to disclose any risk, including climate-related risks, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. BIO urges the Commission to strongly consider updates to current guidance on climate-related risks disclosures as a pathway to meeting the purpose[11] of the proposal in a way that minimizes unintended consequences. In addition, updated guidance would enable the Commission to clarify the range of climate-related risks registrants need to evaluate for materiality, such as geographical or physical risk, without establishing such a significant set of disclosures and organizational changes as proposed.

However, most companies that already report on sustainability issues, such as climate change, already do so in separate reports that allow companies to provide said information in the context of the company's mission, operations, opportunities, and risks. This way investors have the full context of climate-related metrics within one, dedicated place instead of spread across Form 10K.

In addition, as the Commission notes, the current ecosystem of GHG emission reporting, audit, and assurance is "evolving and unique" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data." Essentially, the Commission is compelling industry to implement disclosures using service providers that are not accredited or verified by regulators to implement calculations and frameworks that have not yet been agreed upon or harmonized globally.

Finally, international standard setters, such as the Sustainability Accounting Standards Board (SASB), has already indicated that climate risks are not material for the therapeutics industry, as discussed in the next section. These results were corroborated by an internal BIO survey, which revealed that almost two-thirds of our members believe that climate change poses no material financial risk to their respective businesses. Accordingly, over two-thirds say that they do not

11 The Commission's stated purpose of the proposed rule is to *"require registrants to identify their climate-related risks that are reasonably likely to have a material impact on the registrant's business or consolidated financial statements over the short, medium, and long-term and describe the actual and potential impacts of those risks on its strategy, business model, and outlook."*

disclose climate-related risks in any report. In fact, 11% of our members reported that they have ever been urged by their investors to disclose climate change risks.

Reporting Frameworks

The Commission noted multiple times that the SASB standards are the "benchmark for financially material disclosures[12]" and "guide disclosures of financially material sustainability information by companies for their investors.[13]"

It is for this reason that, according to the International Sustainability Standards Board (ISSB), 69% of S&P 500 companies, 54% of the FTSE 100 companies, and 54% of the S&P Global 1200 use the SASB standards.[14] It is worth noting that SASB, and ISSB standards, are also based on the Taskforce for Climate-related Financial Disclosures (TCFD).

One can thus conclude that companies have chosen to implement the SASB / ISSB reporting standards because a consortium of international investors and industry experts, together, concluded on what is material for a given industry.

Simply put, the most widely implemented sustainability and climate reporting standards in the world, used by both investors and registrants, have illustrated that climate risk materiality varies across the biotechnology industry and have specifically concluded that climate risks are not material to companies developing medicines (therapeutics).

The SASB climate risk technical bulletin, in which the SASB/ISSB maps recommended materiality standards linked to the TCFD framework, includes the same climate risk categories the SEC proposes, including Acute and Chronic physical risks, transition risks and regulatory risks. This SASB Bulletin shows that climate risks, across categories, are not material risks for the therapeutics industry as illustrated in the SASB table below.

[12] Supra note 1
[13] Supra note 1
[14] https://www.sasb.org/

		CLIMATE RISK CATEGORY		
SECTOR	INDUSTRIES	PHYSICAL	TRANSITION	REGULATORY
HEALTH CARE	Biotechnology & Pharmaceuticals			
	Health Care Delivery			
	Health Care Distributors			
	Managed Care			
	Medical Equipment & Supplies			
	Drug Retailers			

SASB Climate Risk Technical Bulletin

The technical bulletin also takes the materiality analysis a step further by outlining how these identified climate risks could impact companies financially, including "including current and future effects on a company's financial condition, operating performance, and its risk profile. The financial implications of climate risk can be grouped into three general categories: income statement impacts, balance sheet impacts, and risk profile impacts.[15]"

Even within the context of a materiality assessment for the probable financial impacts of climate risk to biotechnology companies developing medicines, the SASB / ISSB consortium determined that revenue and operating costs, expected asset impairments and other balance items, and the probable financing risks, creditworthiness, and divestment risks associated with a range of climate scenarios were not financially material.

As the chart below shows, the financial impact channels of climate risks did not include the biotechnology industry in their transmission channel analysis.

SECTOR	INDUSTRY	INCOME STATEMENT	BALANCE SHEET	RISK PROFILE
HEALTH CARE	Health Care Delivery			
	Health Care Distributors			
	Managed Care			
	Medical Equipment & Supplies			
	Drug Retailers			

SASB Climate Risk Technical Bulletin

While the technical bulletin implies biotechnology falls solely within the health care sector, a complete picture of the industry must also include aspects of the renewable resources & alternative energy sector, the resource transformation sector, and certain aspects of the consumer

[15] Supra note 6

goods sector. It is critical to understand this, as to date, no reporting framework has established a single industry standard that is wholly reflective of the entire biotechnology industry. Given the reliance on such standards throughout the proposal it is important that the Commission understand that existing reporting frameworks are not universally applicable to meeting the needs of all sectors.

This challenge extends to TCFD and the GHG Protocols cited by the Commission as the standards upon which the rules have been crafted. In addition, despite current voluntary use of the TCFD and GHG Protocols, they have not been certified officially nor does the SEC oversee TCFD nor GHG Protocols in the way SEC oversees the FASB.

If the SEC wishes to require registrants to use the GHG Protocols methodology, or any other voluntary protocol, despite acknowledging the evolving landscape of GHG emissions reporting, then the Commission should take separate regulatory action to do so. All stakeholders should be provided sufficient notice and comment opportunity to respond to the proposal requiring use of the GHG Protocols or other voluntary methodology that has not been certified or otherwise subject to regulatory oversight.

Finally, BIO supports the proposal to establish an alternative reporting provision for foreign private issuers based on global sustainability reporting standards, such as those being developed by the International Sustainability Standards Board (ISSB), which would mirror the SEC's current alternative provision for financial disclosures based on IFRS accounting standards. A consistent global baseline for climate-related disclosures would benefit both international companies and investors by allowing for standardized and comparable information across jurisdictions. We recommend the SEC adopts such a provision for foreign private issuers that is aligned with material elements of the ISSB standards and/or other recognized climate-related reporting standards that may apply in the company's home jurisdiction.

Small and Emerging Companies

As drafted, the proposal raises a range of questions specific to the implementation challenges faced by small and emerging companies. Those challenges include, but are not limited to, the role of the capital formation cycle and the nature of the R&D pipelines in the industry. In recognition of those challenges BIO strongly supports the exemption of SRCs from all climate-related reporting. BIO also encourages the Commission to extend EGC exemptions from all climate-related reporting.

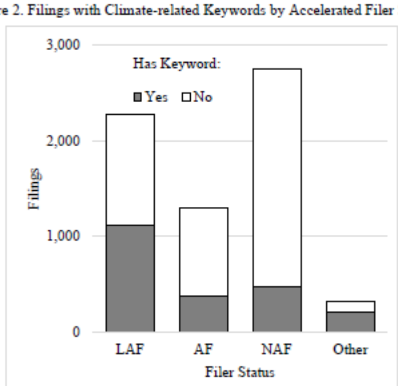
Emerging biotechnology companies will be forced to spend hundreds of thousands of dollars each to *seek* materiality, restate financial statements, calculate GHG emissions and intensity, implement board-level oversight, restructure organizational operating structures, and seek audit and assurances with unestablished frameworks to cater to a risk that is not found to be material for the therapeutics (medicine) industry and has yet to be determined for other aspects of the broader biotechnology industry.

Additionally, the Commission acknowledges that small companies largely do not already have systems in place to report on climate-related financial disclosures[16] and goes on to state,

> "To the extent that they are not already gathering the information required to be disclosed under the proposed rules, registrants may need to *re-allocate in-house personnel, hire additional staff, and/or secure third-party consultancy services. Registrants may also need to conduct climate-related risk assessments, collect information or data, measure emissions (or, with respect to Scope 3 emissions, gather data from relevant upstream and downstream entities), integrate new software or reporting systems, seek legal counsel, and obtain assurance on applicable disclosures*.[17]"

The Commission further acknowledges that small companies will shoulder the greatest financial burden and estimates that compliance would cost between $490,000 to $640,000 to implement in the first year with $120,000 to $180,000 in estimated internal costs and $350,000 to $460,000 in estimated outside professional services costs.[18] But these do not include estimates for hiring additional staff, acquiring and integrating new systems, and the costs of new board and

16 Figure 2. Filings with Climate-related Keywords by Accelerated Filer Status



at Supra note 1

17 Supra note 1

18 Supra note 1

management structures dedicated to climate reporting. In fact, a survey of BIO members showed that 71% of BIO members would be forced to hire third-party consultants, and 56% believed that the Commission has underestimated these expected costs with 40% expecting to pay between $500,000 and $1,000,000.

The Commission also mentions that service providers have estimated that "low maturity" companies, or those that have "no formal understanding of GHG emissions calculations and have no related policies or programs in place[19]" should expect to bear higher costs associated with seeking professional services in GHG emissions reporting.

Separately, the nature of an emerging biotechnology company's consolidated financial statements would make the proposed new line items required by the proposal confusing for investors, auditors, and assurance providers alike.

Small and emerging companies in the biotechnology industry may not have product revenues for years, if ever, and must raise capital throughout their lifecycle to finance ongoing R&D pipelines. Revenue recognition accounting, as it is applied in the emerging biotechnology industry, may lead to highly volatile and incomparable climate-related financial metrics. The most common revenue recognized in this sector is that from capital raising (either via partnerships or follow-on issuances), and companies do not raise money every year.

The desire for an appropriate alternative, such as total assets[20] as recommended by the Commission in the proposed rule, may compel further confusion. Total assets, which in the biotechnology industry consists of mostly cash and cash equivalents, are the main assets of a small biotechnology company and these fluctuate across the sector to address R&D funding needs, which would make the Commission's intention for consistency very difficult to achieve. (This is further explained in Reporting Metrics Section below.)

Aligning the dynamic nature of R&D pipeline financing with the requirements of the regulation, as proposed, may challenge a small biotechnology company's ability to meet the Commission's intended goals. Cash levels in the biotechnology industry are not uniform or consistent, even across companies leveraging similar types of science. This spectrum of cash levels and burn rates is part of the fundamental analysis of the industry, which is calculated by most biotechnology

[19] Id.

[20] "If the registrant has no revenue for a fiscal year, it would be required to calculate its GHG intensity with another financial measure (*e.g.*, total assets), with an explanation of why the particular measure was used. Similarly, if the registrant does not have a unit of production, it would be required to calculate its GHG intensity with another measure of economic output, depending on the nature of its business (*e.g.*, data processing capacity, volume of products sold, or number of occupied rooms) with an explanation of why the particular measure was used." – Supra note 1

specialist investors and analysts. Similar analyses are conducted by analysts for other industries. With such a diversity of cash levels and cash burn rates, the application of climate-related forecasted impacts on financial statements will not be consistent or comparable.

Furthermore, and crucially, BIO supports an alternative threshold for climate-related reporting. As discussed in Question 137, the Commission should align the statutory definition of SRC with the market definition by updating the public float threshold to $2,000,000,000. Defining SRC as companies with less than $100,000,000 in revenue and less than $2,000,000,000 in public float, (a) keeps with the revenue threshold of SRC, and (b) aligns current definition of SRC with market practice for small companies, which is defined as a company with market capitalization (public float) less than $2,000,000,000. The same public float threshold should also apply to emerging growth companies, which would help to align further regulatory definitions with market definitions and practice.

Data Collection and Reporting

As the Commission notes, the current ecosystem of GHG emission reporting is "evolving and unique[21]" and "in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data.[22]" Because the Commission is compelling industry to implement disclosures in a shifting landscape with a multitude of service providers that have not been validated or verified by regulators, both investors and registrants would be better served with maximum flexibility and protections under safe harbors given the inherent need to rely on estimation and forecasting.

The Commission acknowledges that the current landscape is fraught with liability across the entire reporting, auditing, and attestation of climate risk disclosures and yet the Commission is only providing narrow safe harbors. The Commission writes,

[21] "Although we are proposing certain minimum standards for attestation services, this proposal does not aim to create or adopt a specific attestation standard for assuring GHG emissions, just as this proposal does not define a single methodology for calculating GHG emissions. This is because both the reporting and attestation landscapes are currently evolving, and it would be premature to adopt one approach and potentially curtail future innovations in these two areas. The evolving nature of GHG emissions calculations and attestation standards could suggest that it may also be premature to require assurance."

[22] "Nevertheless, *the evolving and unique nature of GHG emissions reporting involves and, in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data.* As such, requiring a third party's attestation over these disclosures would provide investors with an additional degree of reliability regarding not only the figures that are disclosed, but also the key assumptions, methodologies, and data sources the registrant used to arrive at those figures."

> “Nevertheless, the evolving and unique nature of GHG emissions reporting involves and, in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data.”

There is too much willful reliance on third-party service providers that have not been vetted, accredited, or certified by regulators as trustworthy providers of assessments, verifications, and services for the greatest change in accounting and corporate reporting in a generation. Estimates based on various unapproved sources and unapproved methodologies without appropriate safe harbors is dangerous for registrants.

BIO is concerned that the Commission has not adequately provided for exemptions and phase-in periods for small companies to adapt to the proposed reporting requirements. In fact, 67% of BIO members surveyed said that they currently do not report on carbon emissions, and a similar majority have significant concerns with the ability to collect and accurately report without significant liability. This challenge is compounded by the evolving nature of the reporting and attestation landscape.

As the Commission noted through the Economic Analysis section, there is an expectation for implementation prices to fall over time. The Commission should extend lengthier phase-ins and more exemptions to allow for the market to settle on standards and for prices adjust.

This brief respite and on-ramp will also provide small companies with the confidence that those service providers that remain in the market have been validated by large, seasoned filers and investors alike to provide accurate, adequate, and accepted services. This is crucial as the Commission provides very limited safe harbors for the use of so many third-party providers of data and services that will be required to comply with these new regulations.

Where reporting is determined to be material and necessary, registrants should generally be allowed to report according to their existing reporting schedule, which is by fiscal year. However, the Commission should align to the greatest extent feasible with existing GHG reporting timelines as it relates to registrants already required to report emissions data. For example, the reporting deadline for the Greenhouse Gas Reporting Program (GHGRP) administered by the Environmental Protection Agency (EPA) is March 31st.

Scope 3 Emissions in Biotechnology

As discussed above, the biotechnology ecosystem is concentrated with small, pre-revenue companies that are heavily focused on research and development. Compelling these companies to implement new and costly corporate structures to monitor non-material risks to their respective organizations is already quite the undertaking and falls far afield of the SEC's mandates. However, the Scope 3 emissions portion of the proposed rule would impose the most significant burden on these companies, and, indeed, most companies. Accordingly, BIO agrees that smaller reporting companies (as defined herein) should be exempt, and BIO supports the safe harbors for Scope 3 disclosures. BIO also vigorously recommends that emerging growth companies be provided with these exemptions.

Effectively, the Commission is requiring that corporate managers become experts in and responsible for the analysis of the climate economics and emissions drivers of adjacent industries. Historically, that has been an investor's job.

Companies will be now responsible for forecasting the emissions of companies in other industries, hypothesizing the expected emissions path of those companies, and incorporating these estimates into internal forecasts to report to investors. While this is the business model for some companies, most companies find the risks and liabilities involved are significant.

BIO is concerned that the Commission is forcing companies to shoulder the burden, responsibility, and liability for accumulating, forecasting, reporting, and independently assuring emissions forecasts based on estimates from adjacent industries. It seems that investors do not have any responsibility in analyzing companies and industries when it comes to emissions and climate risks.

For example, downstream of the biotechnology industry is, literally, the entire world, which includes governments. Medicine and food must reach every corner of the world, from metropolitan centers to the most desolate places on earth. What is more material for a company in this scenario, the fact that medicine and food reached these patients or estimates of the emissions it took to reach these rural communities, including emissions estimates from all the international organizations (who do not report on their emissions) that are part of the delivery?

Any biotechnology therapeutics company that sells medicine to the United Kingdom's National Health Service (NHS) or the U.S. government's Tricare program, for example, will struggle with creating and reporting Scope 3 estimates, assumptions, and methodologies. The sale is material, but the value chain emissions tied to the NHS's transportation and use of the medicine is not.

For instance, should a startup biotechnology company in Arizona that gains the UK's NHS as a customer be forced to estimate and report on the percentage of the NHS's 25 million tons of CO_2-equivalents that pertain to their product?[23] The fraction would be negligible, but the amount of capital, time, and other resources required would be significant. More importantly, what value does that exercise add to investors of the biotechnology company?

Nowhere in the NHS's decarbonization plan does the NHS determine that the production and value chain of small molecule or biological medicine developers contribute significantly to its emissions.[24] Hence, in this representative example, the NHS's emissions and its decarbonization plan are not material to the small biotech's operations or future finances. Why then would the SEC compel biotherapeutics companies that count the NHS as a customer to hire consultants to estimate and report on Scope 3 emissions stemming from having the NHS as a customer?

Finally, a survey of BIO's members confirmed the difficulty of gathering this information. A full 100% of survey respondents reported that it would be difficult to collect Scope 3 data from their global suppliers and would require hiring third parties. In addition, the survey revealed widespread concern among BIO members that the Commission's proposed safe harbors for Scope 3 emissions reporting would NOT mitigate liability.

Safe Harbors

BIO strongly urges the Commission to enshrine all proposed climate-related disclosures in the Private Securities Litigation Reform Act (PSLRA) safe harbors, including GHG emissions, GHG intensity, transition plans and targets, internal strategies, financial impacts, and other proposed disclosures, statements, and supplemental information.

The Commission outlined numerous times within the proposed rule that most aspects of the proposed reporting requirements is "still evolving," including the audit and assurance aspects of the proposed rule. The Commission should therefore exclude the proposed rules from ICFR requirements until such time as the Commission has established appropriate guidelines for audit and assurance. Finally, the Commission should keep with the spirit of the JOBS Act and include climate-related disclosures and financial-impact disclosures in the emerging growth company exemption.

[23] https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(20)30271-0/fulltext?rss=yes, and NHS "Delivering a 'Net Zero' National Health Service" report, October 2020

[24] The NHS focuses on anesthetic gases and inhalers as its largest emitters from the medicines category (as is the case for all hospital systems).

Further, as noted elsewhere in these comments, the biotechnology industry's nuance will make certain proposed metrics unusable for generalist investors, and, we fear, may cause consternation and possible litigation attributed to nothing more than a lack of understanding of the sector. For these reasons as well, the Commission should broaden the safe harbors to include all climate-related financial disclosures. Should the Commission go so far as to mandate immaterial disclosures, they should be provided separate from traditional financial statements and included in supplemental information that are protected under safe harbors.

Climate-Related Risk & Opportunity

As discussed above, the material nature of climate-related risks will be different for various sectors of the biotechnology industry. In addition, for some registrants' climate-related opportunities are foundational to the operation of the company. As such, registrants should have the option to identify and illustrate the relationship between climate-related risk and opportunities, identified as material, as it relates to significant changes made to, its products or services, supply chain or value chain, activities to mitigate or adapt to climate-related risks, including adoption of new technologies or processes, expenditure for research and development, and any other significant changes or impacts.

Furthermore, existing guidelines and Commission guidance already require companies to disclose and discuss any risk, including climate-related risk, that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements. To require all registrants to disclose or discuss the process for identifying, assessing, and managing climate-related risks, as proposed could be both duplicative and challenge traditional interpretations of materiality. For those registrants that determine climate-related risk is material to their business such process related disclosure should be optional.

BIO urges the Commission to take into consideration that the wide range of enumerated climate-related risk considerations included in the proposal, as drafted, may result in creation of new risk for registrants particularly in the realm of liability and cost. For this reason, it is imperative that the Commission adhere to the current standards of materiality and allow companies to report only on material effects of climate change on financial statements.

In furtherance of that goal, BIO encourages the Commission to ensure that there is no overlap in reporting requirement across federal and state government agencies. To the extent that there is overlap, such as with the EPA, the Commission should work with other federal and state agencies to ensure common reporting standards are in place and shared across agencies. Insofar as there is overlap, registrants should not have to disclose to two separate agencies. Further, if the EPA has established a requirement for registrants to disclose certain emissions, which are then published for public consumption, then there is no need for the Commission to require further disclosures of risks and calculations that are not material for securities regulators to hold. Should the Commission determine there remains a need for specific emissions disclosures on financial statements they should be predicated on materiality and not reliant on arbitrary thresholds especially.

Additionally, the Commission should refrain from including definitions discussed in the proposal that may already be widely understood in the context of existing GHG emissions reporting. For example, the EPA already provides guidance on the definition of Scope 1, Scope 2, and Scope 3 emissions. As a result, the SEC does not need to further define terms such as "upstream costs." The proposed examples provided regarding the financial impact metrics clarified how to contemplate reporting in the event a climate-related event or climate trend is found to be material enough to warrant disclosure.

Should the Commission finalize components of the climate-related risks disclosure and reporting proposal, BIO would urge that in addition to adhering to current standards of materiality that the Commission focus required disclosure on common elements across registrants and sectors of the economy. For example, not all registrants will have established or seek to establish a price of carbon. In addition, the Commission should ensure that required disclosure does not duplicate existing pathways of communication between registrants and investors or investor analysts. Current guidelines and standards already require registrants to provide disclosures on the risks and events, such as climate-related events, that alter capital expenditures and the cost of capital. As such, registrants already raise with investors when the cost of capital changes and the impact of those changes on specific, material line items.

Reporting Metrics

BIO supports and strongly recommends that the Commission continue using the materiality standard, as it is traditionally understood, for company reporting on the effects of climate-related events and transition activities on financial statements and operations, including if there are material changes to how companies estimate, calculate, or develop assumptions and methodologies for any material disclosure. The Commission must ensure that the means of such reporting not be undermined by mandated use of metrics that are arbitrary or have a significant potential for causing confusion with generalist investors. For example, the SEC should ensure that required metrics not be duplicative or involve significant overlap as would occur in reporting both financial impact metrics and as specific expenditure metrics.

While the Commission has used various thresholds to trigger different reporting requirements, the Commission's proposed requirement of a one percent threshold trigger constitutes the Commission creating a new definition of materiality, which is intended to supersede the current definition that has been established by case law and subvert a company's shareholders as the stakeholders responsible for dictating what is material to them. BIO is concerned that the SEC is endeavoring to uproot the established interpretations of materiality.

BIO contends that a one-percent impact may not be material for every company of every size in every industry. BIO stresses the need for the Commission to adhere to the current standards of materiality and allow companies to report only on material effects of climate change on financial statements. Historically, a one-percent deviation of any consolidated financial statement line item would never reach the level of materiality for a broad investment public. Furthermore, a one-percent expenditure is seldomly critiqued by investors. Why, then, should registrants be compelled to report a trigger that historically would never be considered important by an investor?

As proposed, BIO further contends that the climate-related financial statement metrics and GHG intensity metrics have significant potential to cause confusion among generalist investors and will require registrants to provide calculations and metrics that have been traditionally part of the roles and responsibilities of an industry analyst / investor.

Requiring registrants to calculate GHG intensity as proposed, will not provide for adequate or uniform comparisons across biotechnology companies for all investors. Only specialist investors will be able to understand the volatility of the contemplated ratios and how to truly compare between biotechnology companies (as is currently the case).

Biotechnology companies with no revenue or units of production will be put into a disadvantageous position as the denominator of such calculations is inherently volatile and entirely predicated upon the cash raising cycle. For these reasons, BIO strongly urges the Commission continue using the materiality standard for climate-related company reporting and agrees that companies with no revenues or units of production should not disclose GHG intensity.

For context, alternative asset metrics, such as total assets, are highly volatile and cyclical line items as they are comprised of cash, cash equivalents, and short-term investments. These line items are not uniform or consistent across the biotechnology industry, even among companies leveraging similar types of science or companies in the same therapeutic category (e.g., oncology) for those developing medicines.

Small biotechnology companies, which spend heavily on R&D, use cash at an accelerated rate and raise new funds frequently but not in defined patterns or amounts. This spectrum of cash levels and burn rates is part of the fundamental analysis of the industry, which is calculated by most biotechnology specialist investors and analysts. Similar analyses are conducted by analysts for other industries. With such a diversity of cash levels and cash burn rates, the application of climate-related forecasted impacts on financial statements will not be consistent or comparable.

Since the denominator of these proposed intensity metrics will be composed of these highly volatile and highly cyclical line items, this means that over time, by virtue of the business model and industry, emissions, emissions-intensity, and climate-related financial metrics will deteriorate[25] until capital is raised once again.

In other words, climate-related financial disclosures will ebb and flow with the capital raising cycle. Most generalist investors will not know this nuance when it comes to investing in biotechnology companies and has the potential to detract generalists from the biotechnology sector as it will introduce yet another layer of complexity.

Furthermore, the Commission does not require companies to conduct a DuPont analysis, intrinsic value calculations, return on invested capital, return on capital employed, liquidity ratios, current ratios, or any other ratio that helps analysts and investors understand and compare financial statements. While many companies may provide some of these ratios, they are not mandated by securities regulators. This should also be applied to climate-related financial metrics as they are not material to all companies, may cause significant confusion for generalist investors researching technical industries, and will leave companies open to liability.

BIO urges the Commission to ensure that, where material, reporting metrics do not create an unnecessary shift in regulatory burden onto reporting companies. The Commission, for the first time, has requested that companies specifically analyze, discuss, forecast, and report on how an exogenous shock and/or macro factor (climate change) will impact their respective businesses and consolidated financial statements over various time horizons. The analysis of macro factors on financial statements is the job of investors and industry analysts. Registrants should not be made to do this level of analysis for investors, assuming the liabilities in the process.

[25] As the denominator (cash level) falls and numerator (emissions) stays basically unchanged, the ratio increases and sends a false signal to investors that the company may be emitting more GHGs or GHG intensity may be increasing over time, even though nothing has really changed except for cash levels ("total assets").

As it relates to filing of historic data, BIO understands that starting points matter. However, BIO contends that asking small companies to submit historical years is a significant and costly burden. If disclosures of methodologies are already included as part of the disclosures, then investor should be able to extrapolate. BIO remains concerned that the Commission is requiring registrants to fulfill the analytical role traditionally completed by industry analysts and investors. Furthermore, private companies seeking to IPO should not have to provide climate-related disclosure in Form S-1 as many companies will be using capital raised in an IPO to fulfill all of these requirements. There is little expectation for venture capital investors to provide funding to finance the creation of organizational structures that are required to satisfy a different pool on investors.

Attestation

Given that the Commission has acknowledged that the current market for "both the reporting and attestation landscapes are currently evolving" the Commission should allow for significant transition periods to allow registrants, auditors, and attestation providers to catch-up to demand and settle on market standards, which are currently not present.

Attestation requirements, where required, should be phased-in in-line with the spirit of the JOBS Act emerging growth company exemptions. In addition, the requirement should be limited to seasoned issuers and those companies with more than $1,000,000,000,000 in revenue and more than $2,000,000,000 in public float, which (a) keeps with the revenue threshold of SRCs and EGCs, and (b) aligns current definition of SRC with market practice for small companies, which is defined as a company with market capitalization (public float) less than $2,000,000,000.

BIO strongly supports the establishment of global standards for attestation engagement and reporting prior to requiring registrants to utilize them in reporting to shareholders and filing with the Commission. This will go a long way to limit liability and create a level-playing field for all registrants. BIO strongly supports that these standards be created by a recognized body that follows due process procedures, including feedback from all stakeholders, and them making these standards available at no cost. If the Commission is endeavoring to formalize the reporting of climate-related risks, then the Commission should ensure that the reporting, auditing, and attestation frameworks that will be used are standardized, transparent, and well-understood by all stakeholders.

Organizational Structure

While the overall impact of climate-related risk disclosure will vary across registrants and sectors of the economy, BIO remains concerned regarding the burden specifically being imposed on the makeup, compensation, and expertise of boards and management structures. Registrants should be able to, if needed, demonstrate board level commitment without the Commission mandating climate-related expertise be housed within the board. Biotechnology firms, especially small and emerging companies, need to ensure a wide range of highly specialized expertise is demonstrated among a small number of individuals. Current efforts by the Commission to embed multiple new areas of specialized expertise in these boards will create additional barriers for companies already having difficulty identifying individuals to serve.

The proposed rule for board-level involvement and oversight seems more appropriate as a requirement for index inclusion. This is the most efficient mechanism for ensuring that larger companies have board representation for this matter. For example, S&P 500, Dow Jones Industrial Average, MSCI, Russell, Wilshire, and CRSP Indices can mandate that in order to be included in their respective index, a company must fit the market capitalization and board structure requirements.

In addition, the Commission should ensure that any board- or management-level requirements included in the proposal, if finalized, be framed to ensure that a company's management is focused on matters that are material to the operations and finances of the company. The SEC should not mandate that every company in the United States be required to expand management structures to accommodate concerns that are not material to a company.

The Impact of Regulation on Small Business Capital Formation

BIO urges the Commission to view their regulatory agenda with the hindsight of lessons learned from past waves of regulation, the consequences they had for capital formation and capital markets, the significant costs to small companies and the knock-on effects to local economies, and the eventual need to roll back regulations to more meaningful and more effective levels. This proposed rule will compel action which will increase the cost of capital for smaller companies and increase capital expenditure on greenhouse gas emissions and climate risk service providers. This is in addition to the costs and liability already proposed by the Commission's other proposed rules.

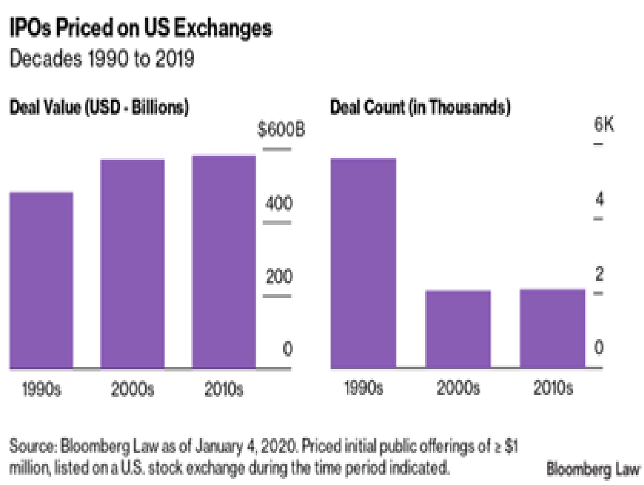
The net consequence of heavy regulatory reporting burdens for public companies are two-fold. (1) Fewer companies will join public markets (particularly since climate risk disclosure are required for Form S-1 with no phase-in or protections from an emerging growth company designation), and (2) the companies that do become public will be large in order to absorb the burdens associated with being a public company.

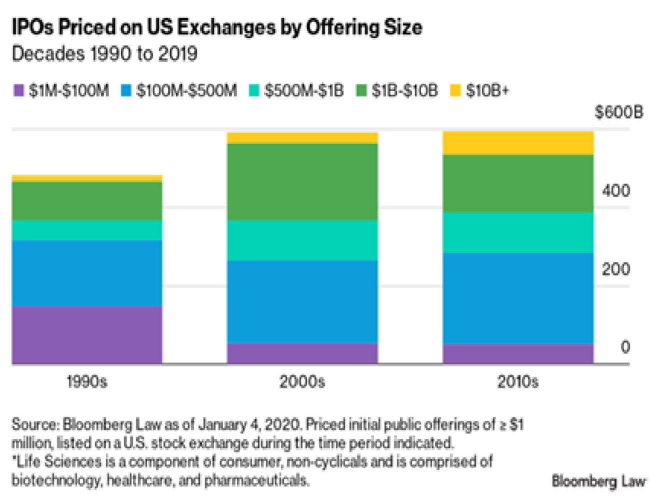
Put another way, more regulation means you create larger companies. This is a natural consequence of requiring more capital to support a larger, more costly operating structure to meet the demands of regulators. This was the result of Sarbanes-Oxley. Similarly, in the wake of Dodd-Frank, financial institutions and asset managers became much larger.

As the chart below illustrate, in the wake of Sarbanes-Oxley the number of IPOs fell but deal values increased. This means that fewer companies went public, but those that did tended to be large. Put another way, the consequence of regulatory waves is the creation of larger companies and industry consolidation to absorb effectively costs and operations.

From the 1990s to the 2000s the number of IPOs fell by more than 60 percent.[26] Another way to look at it is by breaking down the deal values by offer size where one can note that since the 1990s the number of companies seeking $1 million to $100 million collapsed.[27]

Congress had to enact new legislation, most crucially the JOBS Act of 2012, to reignite the IPO market, particularly for smaller companies. This is concerning, given that support for legislation like the JOBS Act is no longer as bipartisan as it once was.





[26] https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-three-decades-of-ipo-deals-1990-2019
[27] Id

The current wave of regulation is threatening to repeat the earlier cycles in capital markets and capital formation. It will become necessary for Congress to enact new ways to incentivize going public because of the significant cost and onerous, duplicative, reporting associated with being a reporting company. Such a feat will be exponentially more difficult in today's climate than when the JOBS Act was first enacted.

While each of the Commission's proposed rules have merit and address serious issues, BIO is concerned that the Commission is not analyzing the aggregate effects and consequences of the entire regulatory agenda.

Conclusion

BIO thanks the Commission both for undertaking this important work and for the opportunity to provide feedback and comments on the proposed rule. BIO remains highly concerned with the financial impact of the proposed rule on small reporting and emerging growth companies. BIO recommends that the Commission align the definition of smaller reporting company with the investor definition of small company (market cap less than $2,000,000,000) and provide for exemptions. BIO is concerned that the proposed rule is highly reliant on an ecosystem of service providers that have not been accredited or certified by regulators as adequate providers of the data, systems, consulting services, audit, attestation, and governance advice that is required for this proposed rule to be successful. As such, BIO recommends that the full climate disclosure proposed rule qualify for safe harbors. BIO is also concerned with the consolidated financial statement reporting proposals as (a) a one-percent threshold is a negligible fluctuation for most companies, (b) is imposing artificially one percent as a materiality threshold, and (c) intensity metrics and other financial-related ratios are too volatile for the biotechnology industry and should be omitted from the final rule. BIO looks forward to working with the Commission on these important issues.