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Office of the Secretary
PCAOB
1666 K Street N.W.
Washington, D.C. 20006-2803

Re: Rulemaking docket matter No.34: Concept Release on Possible Revisions to PCAOB Standards Related to Reports on Audited Financial Statements

Dear Board Members:

Eli Lilly and Company ("Lilly") appreciates the opportunity to comment to the Public Company Accounting Oversight Board ("PCAOB") on the Concept Release No. 2011-003 on Reports on Audited Financial Statements. Lilly is a large, multinational pharmaceutical company, with presence in over 50 country jurisdictions, and creates and delivers innovative medicines that enable people to live longer, healthier, and more active lives.

Lilly commends the PCAOB for working to revamp the existing Auditor's Reporting Model in an effort to increase transparency and relevance to financial statement users ("users") while not compromising audit quality. We agree that any changes to the auditor's report should be based upon the principles of maintaining audit quality and adding value to the users while also focusing on objective communications from the auditors and being cost effective. While we believe the current "pass/fail" model is effective, we do agree with the PCAOB that there are some potential enhancements that could make the auditor's report more transparent and relevant for the users. We believe that certain proposed changes could potentially add value to the reporting model and enhance communication to users by improving the content of the auditor's report while retaining the current "pass/fail" model.

However, we believe that certain proposed changes, in particular the Auditor's Discussion and Analysis ("AD&A") and assurance on information outside of the financial statements, could have a significant adverse impact to companies, auditors and users. We appreciate that the PCAOB has taken into consideration the issues raised by stakeholders through the outreach that was conducted. Yet, we are very concerned that these particular proposed changes, if adopted, could change the fundamental role of the auditor, impact transparency between auditors and management and/or lead to confusion of users among other concerns addressed throughout this response.

We address each of the alternatives and our thoughts and concerns in further detail below.

Alternative 1: Auditor's Discussion and Analysis

We strongly oppose the AD&A alternative proposal, which would include a supplemental narrative report with the intent of providing investors and other users with a view of the audit and the financial statements "through the auditor's eyes." The alternative would allow the auditor to discuss views regarding significant matters such as audit risk identified in the audit, audit procedures and results, auditor independence, auditor's views on the company's financial statements including management's judgments and estimates, accounting policies and practices, and difficult or contentious issues, including "close calls". In addition, the auditor could highlight areas where the auditor believes management could have applied different accounting or disclosures.

Management's role is to determine the appropriate accounting policies and estimates and communicate through the financial statements while the audit committee's role is to provide governance and oversight. The auditor's role is to audit the financial information provided by management to ensure that it is materially accurate and not to act on behalf of management or the audit committee. The proposal, as described by the PCAOB, appears to be mixing the roles within these groups which would be unacceptable under current guidance and is contradictory to the roles that currently exist. This alternative would require that the auditor take on more of a governance and oversight role for the company that they are auditing, which could impair independence and naturally bring rise to a number of other issues. We strongly believe that the communication described within this alternative is the responsibility of management under the oversight of their audit committee and not that of the auditor.

We also question who would truly benefit from these additional details being provided when it is concluded that the financial statements are "presented fairly in all material respects." There are numerous estimates and judgments inherent in our financial statements. The role of the auditor is to opine on the reasonableness and consistent application of accounting principles to arrive at an appropriate conclusion. If there are unresolved differences presented to an audit committee then that should be disclosed, however, if there are no differences, we see no value for added discussion.

It is important to understand that many accounting issues are very complex and unique requiring much discussion and research to determine the appropriate accounting treatment. In fact, many times with complex accounting issues, local audit teams must reach out to their national accounting experts because the answers are not obvious. Thus, we believe this alternative is very dangerous. Management is responsible for the financial statements, accounting policies, financial estimates, etc. and there has been a significant effort to ensure that auditors are not making decisions on behalf of management. However, if the auditors are required to disclose their views and their process to understand, discuss and conclude on the accounting policies and estimates, there is a risk that the auditors become the ones who ultimately make the accounting policy and estimate decisions.

If this alternative were adopted it could require a considerable amount of time between management and the auditor to reconcile differences between company disclosures and the AD&A. If the differences are not able to be reconciled this would cause confusion among users. Additionally, requiring the auditor to provide this type of information to investors will likely impair transparency and openness in discussions and increase tension among auditors, management, and the audit committee thereby inhibiting information that is provided to users.

The preparation of an AD&A would substantially increase the scope of the auditor's responsibilities and could adversely impact the auditor's financial statement focus. Additionally, this alternative would bring about the potential for auditors to discuss information about the company that might be deemed proprietary or highly sensitive to a company's competitive industry position which would lead to increased liability for the auditors. As a result of the increased liability, significant expertise and time from auditors, involvement of their national offices and legal counsel would be required in order draft the narrative for public use to mitigate potential legal exposure, which would serve as a significant distraction from the audit. With the already tight reporting deadlines, attempting to complete this additional report would present challenges in terms of our ability to meet current reporting deadlines. All of these factors would promote the use of boilerplate language within the AD&A to avoid legal issues and create efficiency in the reporting process, which would undermine the purpose of providing the additional commentary.

Additionally, we believe that it would be very difficult for the PCAOB to develop an appropriate framework and once developed, whether the framework could be consistently followed by auditors when disclosing information of such a highly subjective nature. Requiring auditors to present information of this nature could result in misleading reports; making it difficult to have comparability among financial statements and causing confusion about the auditor's pass/fail opinion. In today's pass/fail model the unqualified opinion implies that all material matters were resolved and the financial statements are materially accurate and presented fairly. Highlighting this additional information (e.g. close calls, contentious issues, etc.) would suggest a higher level of importance to the issue(s) than is warranted since users would not be privy to the dialogue that occurs between the auditor, audit committee and management in which additional context and perspectives are communicated. This also raises the question of who would be responsible for "auditing" the information provided by the auditor within an AD&A to ensure that it is reliable and not misleading.

We do not believe this proposal meets the defined principles of maintaining quality, adding value, providing objective communication and being cost effective. Our most significant concern identified with this proposal is the impact to the auditor's independence, which may be impaired, if the auditor takes on a role in governance, deciding on accounting policies and making complex accounting judgments. Additionally, the AD&A proposal is potentially confusing to users due to the mixed messages of having an unqualified opinion but a lengthy and complex discussion in the AD&A regarding accounting issues that may be difficult to explain to users that are not experts in those areas. In addition, the AD&A may result in different disclosures between management within MD&A and the auditors within AD&A as well as negatively impacting the relationship between the auditors, audit committee and management. The results will reduce the audit quality and reduce the value to the users. Also, the AD&A is extremely subjective in nature potentially leading to inconsistent and incomparable financial statements which does not meet the principle of providing objective auditor communication. We believe that this proposal will result in significant increase in auditor scope and thus, increase in auditor time and costs which does not meet the principle of being cost effective. Lastly, we strongly believe it is management's role to communicate information to investors and users through the financial statements. Only if there is a disagreement between the auditors and the audit committee should the auditor communicate in this nature with investors, similar to the current requirements under SOx for material weaknesses. Therefore, we urge the PCAOB to eliminate this alternative from the proposal.

Alternative 2: Required and expanded use of emphasis paragraphs

We believe that this may be a reasonable approach depending on the scope of the expanded use of emphasis paragraphs. This alternative would mandate the use of emphasis paragraphs in all audit reports and would expand paragraphs to highlight the most significant matters in the financial statements and where these matters are disclosed. Emphasis paragraphs could be required in areas such as significant management judgments and estimates, areas with significant measurement uncertainty, and other areas that an auditor determines to be of critical importance. The auditor may also be required to comment on key audit procedures performed for each matter of emphasis.

Today the auditor communicates the areas of audit emphasis to the audit committee. We would be supportive of limiting the emphasis paragraphs to parallel what is currently communicated to the audit committee as to the areas of emphasis. This should also mirror, in part, the company's critical accounting policies and significant events which are currently disclosed in the Management's Discussion and Analysis ("MD&A") section of the annual report. These should be objective, fact-based descriptions that reference the specific areas of the financial statements where this information is disclosed. We believe that emphasis paragraphs whereby the auditor identifies the areas of audit emphasis, including critical accounting policies and significant events and where they are disclosed could potentially be helpful for users by providing users with a reference to the areas deemed significant by the auditors and impact the financial statements during the period.

However, we do have significant concerns that the emphasis paragraphs, as the proposal currently describes, are too broad and would be used inconsistently if not clearly defined. Similar to our concerns addressed in alternative 1, we believe that it would be very difficult for the PCAOB to develop an appropriate framework outside of the critical accounting policies and significant events discussion, and once developed, whether the framework could be consistently followed by auditors when disclosing information of such a highly subjective nature. Requiring auditors to emphasize areas that don't necessarily require emphasis could result in misleading reports, make it difficult to have comparability among financial statements and cause confusion about the auditor's pass/fail opinion. In today's pass/fail model the unqualified opinion implies that all material matters were resolved and the financial statements are materially accurate and presented fairly.

Additionally, we believe that requiring auditors to comment on key audit procedures performed pertaining to the identified matters would be difficult to communicate in a concise manner and would not provide the user with the full context of the audit strategy thereby confusing the reader rather than providing useful insight. An audit must be evaluated as a whole, not based on individual procedures. Thus, it would make it very difficult for users to understand an auditors overall assessment when highlighting only a few areas. In addition, many of the users do not have the background, understanding or context to properly evaluate the audit procedures. It is important to understand that many significant audit issues and the audit procedures are complex, resulting in local audit teams consulting with their national experts and if the users are not experts in the area, the additional information may be more confusing and potentially, even misleading.

While we do believe that the emphasis paragraphs may provide value and meet the defined principles, we urge the PCAOB to carefully consider the scope of the emphasis paragraphs. We propose that the emphasis paragraphs be limited to the areas of audit emphasis reported to the audit committee, which would include critical accounting policies and significant events during the period, to provide users with a summary of the most impactful areas to the financial statements for the period. This proposal would maintain audit quality, add value to the users by have one place to find the information, provide objective communications from the auditors, while still being cost effective.

Alternative 3: Auditor assurance on other information outside of the financial statements

We object to this alternative which would require auditors to provide assurance on information outside of the financial statements such as the MD&A disclosures, non-GAAP financial measures, and/or information contained in earnings releases.

The information outside of the financial statements allows management to comment on future plans, estimates and goals. Due to the nature of the information provided, the information outside of the financial statements is often times not an area on which the auditor's could effectively provide assurance. We do not believe that this alternative would add value to the process or provide additional comfort to users; however it would substantially increase the scope of the auditor's responsibilities as well as the time and cost of completing the audit. The increase in scope would shift the auditor's focus away from the financial statements, negatively impacting audit quality. Additionally, this alternative would lead to companies needing to furnish periodic filings at an earlier stage of the process, in order to provide the auditors with a chance to complete their procedures prior to the filing deadline which could put a severe strain on companies and auditors during the already tight reporting timelines and could lead to the delay of information being released to the public.

Also, we are specifically not supportive of requiring auditor assurance on the MD&A to cover the critical accounting policies as some proposals have suggested. The information typically included in the critical accounting policies section either discusses policies that do not require audit procedures or covers information that has already been audited within the footnote disclosures. We would be supportive of the auditor report referencing the critical accounting policies, indicating that they have been included in their overall audit procedures. However, we do not believe that providing a separate attestation report on the critical accounting policies within the MD&A would provide any additional benefit to the users.

There are situations where we rely on outside SEC counsel to provide our independent review consistent with Regulation FD. To include the auditors further within this process would require us to provide a significant amount of documentation for their work papers to meet PCAOB documentation standards on areas that do not have any significant impact on the reliability of the financial statements.

We would be supportive of the PCAOB expanding the current external auditor requirements for other information in documents containing audited financial statements as outlined in AU 550 (responsibilities include reading and considering whether such information or the manner of its presentation is materially inconsistent with the financial statements or represents a material misstatement of fact) to cover the press release and other Non-GAAP measures. In addition, we would be supportive of including language within the audit report that communicates the current requirements under AU 550 in order to help users to better understand the procedures being performed and address the points raised by participants in the staff outreach that auditor association may increase reliability and quality of the information provided by management.

We do not believe this proposal meets the defined principles of maintaining quality, adding value, and being cost effective. As a significant portion of the information outside the financial statements, such as MD&A, is subjective, judgmental and forward looking, we do not believe that requiring auditors to provide assurance is value adding or in the spirit of maintaining quality. In fact, there may be numerous pieces of information that are un-auditable. The auditors would also need to spend a significant amount of time and resources on areas that are outside the risks related to the financial statements. In addition, this proposal will result in significant increase in auditor scope and thus, increase in auditor time and costs which does not meet the principle of being cost effective. Therefore, we urge the PCAOB to eliminate this alternative from the proposal, with the exception of considering expansion of current requirements outlined in AU 550 to cover the press release and other Non-GAAP measures.

Alternative 4: Clarification of language in the standard auditor's report

We are supportive of amending the standard audit report with clarifying language that would serve to enhance the report and help users better understand the responsibilities of the auditor and what an audit represents. This alternative would require auditors to provide additional disclosures in the standard audit report to clarify key terms used in the report. Below are the proposed alternatives and our view on each of them as to whether the language around these topics within the auditor's report should be revised to provide clarification on the auditor's responsibilities.

- Reasonable assurance – We are supportive of clarifying the language around reasonable assurance to correspond with the current auditing standard in order to reinforce the concept that an audit provides a "high level of assurance, but not absolute assurance."
- Auditor's responsibility for fraud – We believe that the auditor's responsibility for the detection of fraud should be addressed within the standard auditor's report in order to be more transparent to users. We are supportive of expanding the current language within the report of, "…Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, to include the words, "whether caused by error or fraud" as is consistent with the current auditing standard.

- Auditor’s responsibility for financial statement disclosures – We are supportive of revising the auditor’s report to provide clarification on the auditor’s responsibility for the financial statement disclosures that is consistent with the current auditing standard.
- Management’s responsibility for the preparation of the financial statements – We are supportive of further clarifying the auditor’s report to state that management prepares the financial statements and has responsibility for the fair presentation of the financial statements.
- Auditor’s responsibility for information outside the financial statements – As discussed within the response to Alternative #3, we believe that providing the users with an understanding of the auditor’s current responsibilities under AU 550 would be beneficial and help users to better understand the procedures being performed, which could address the recommendation made during the staff outreach that auditor association with the this information may increase its quality and reliability.
- Auditor independence – We are supportive of clarifying this concept as we believe this could provide users with a better understanding of the auditor’s role and provide more confidence in their judgments and process. Additionally, this could address the belief that auditors are in a unique position to provide relevant and useful information because of the extensive knowledge of the company and industry. While the auditor’s may be in a unique position to provide this inside information, this could potentially undermine the independence of the auditor.

These clarifications outlined above would not alter the scope of the audit nor impact the auditor’s responsibilities; they would however provide additional information to users without changing the fundamental role of the auditor. We believe that this alternative is most closely aligned with the PCAOB’s goal of increasing transparency and relevance to users while not compromising audit quality. We also believe that this alternative is aligned with the principles of maintaining quality, adding value, providing objective communication and being cost effective. The more the users understand of the auditor’s role, the better informed they can be when making decisions.

Conclusion

Again, Lilly supports the PCAOB’s efforts to provide transparency and relevant information to users and believe that certain proposed changes could add value to the reporting model and enhance communication to users through improving the content of the auditor’s report while retaining the current “pass/fail” model. However, we are concerned that certain options, particularly the AD&A and assurance on information outside of the financial statements, could result in a number of unintended consequences and negatively impact that audit process. We again urge the PCAOB to carefully consider and evaluate the impact that each of the proposals and/or combination of proposals would have on the companies and the auditors who would be required to comply with any new standards issued and the related implications. We also urge the PCAOB to carefully consider the cost/benefit of all of the proposed alternatives prior to implementing any new standards.

As part of our conclusion, we would like to suggest that the PCAOB urge the Securities and Exchange Commission ("SEC") to reconsider the definition of an audit committee financial expert as defined under Section 407 of the Sarbanes-Oxley Act of 2002. We believe that it would be beneficial if the definition were clarified to indicate that the individual must possess significant GAAP accounting experience obtained through public accounting experience at the Senior Manager or Partner level or from serving as a Controller, Chief Accounting Officer or similar role that is involved with the preparation of the financial statements. We strongly believe that modifying the definition of an audit committee financial expert could foster more robust conversations and lead to higher quality financial statements.

We appreciate the opportunity to express our views and concerns regarding the concept release. If you have any questions regarding our response, or would like to discuss our comments further, please call me at (317) 276-2024.

Sincerely,

ELI LILLY AND COMPANY

/s/Arnold C. Hanish

Arnold C. Hanish
Vice President, Finance and
Chief Accounting Officer