

Eli Lilly and Company Lilly Corporate Center Indianapolis, Indiana 46285 U.S.A.

www.lilly.com

December 11, 2013

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

Re: PCAOB Rulemaking docket matter No. 34

Dear Board Members:

Eli Lilly and Company ("Lilly") appreciates the opportunity to comment to the Public Company Accounting Oversight Board ("PCAOB") on the PCAOB Release No. 2013-005, *The Auditor's Report on an Audit of Financial Statements when the Auditor Expresses an Unqualified Opinion; The Auditor's Responsibilities Regarding Other Information in Certain Documents Containing Audited Financial Statements and the Related Auditor's Report; and Related Amendments to PCAOB Standards*. 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 understands the PCAOB's objective to revamp the existing Auditor's Reporting Model in an effort to "increase the informational value of the auditor's report to promote the usefulness and relevance of the audit and the related auditor's report". 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 amendments to the basic elements of the auditor's report could 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.

We believe that certain proposed changes, in particular the requirement for the auditor to report on Critical Audit Matters ("CAMs") and additional requirements around "other information" outside of the financial statements, could have a significant adverse impact to companies, auditors and financial statement users ("users"). We appreciate that the PCAOB has taken into consideration the comments raised by stakeholders through the 2011 Concept Release and has chosen not to pursue the implementation of the Auditor's Discussion and Analysis ("AD&A"). However, we are very concerned that requiring the auditor to report on CAMs, if adopted, could significantly increase the scope of the audit, blur the responsibility of auditors, audit committees, and management by changing the role of the auditor and lead to confusion of users among other concerns addressed throughout this response. We are concerned that imposing additional requirements around "other information" outside of the financial statements, if adopted, could also significantly increase the scope of the audit as well as substantially increase costs.

We address our thoughts and concerns in further detail below.

Critical Audit Matters:

We strongly oppose the proposal which would require the addition of a new section within the auditor's report in which critical audit matters specific to an audit would be communicated. The PCAOB defines CAMs as audit matters that involve the most difficult, subjective, or complex auditor judgments; pose the most difficulty to the auditor in obtaining sufficient appropriate audit evidence; or pose the most difficulty to the auditor in forming the opinion on the financial statements. While we support the goal of increasing the relevance and usefulness to investors and other financial statement users, we have concerns about the application of the proposal, the unintended consequences and question if this proposal would help to accomplish the intended goal.

The current proposal leaves a lot of judgment for what the auditors may consider to be 'key' or 'critical' audit issues, which could lead to unintended consequences. We are most concerned about the potential for the auditor to disclose information in their report that the company has not yet reported or is not required to be disclosed by the SEC or FASB, making the auditor the original source of the information. The auditor could identify a CAM around a transaction that has not yet been recorded in the financial statements by management due to timing or facts and circumstances of the item (i.e. restructuring, litigation, impairment of intangibles, etc.). For example, as required by the FASB, we record restructuring charges when they are estimable and probable. Based on the facts and circumstances, the restructuring charge may get recorded in the following year, however, the auditor may elect to disclose this item as a CAM in the prior year audit if it meets the CAM criteria. Disclosing this as a CAM would make it public information before the company would have had a chance to go through the appropriate communication channels and timeline. Additional examples where the auditor could be the original source of information include disclosing the dollar amount of items that are currently not required to be disclosed or disclosing details used to describe the CAM that have not been disclosed in the financial statements. It seems counterintuitive that a company would need to disclose information not because of the accounting standards but because of the potential to appear as a CAM and not elsewhere in the financial statements or footnotes.

Another concern of the proposal is that a CAM may disclose sensitive, confidential or proprietary information such as tax matters including settlement with the IRS, legal matters, restructurings, etc. The auditor may also disclose a CAM that conflicts with current requirements or legislation, such as disclosing significant control deficiencies, whereas only material weaknesses are required to be disclosed today. While the items may have been discussed with the audit committee, it may not be public information. The auditor would be disclosing details of the CAM that are not disclosed elsewhere in the financial statements or footnotes.

If the proposal to require the auditor to identify CAMs is adopted, this would put the auditor in a position under numerous circumstances to be the original source of information to financial statement users and is contrary to the current roles and responsibilities of the auditor. This will blur the responsibility of auditors, audit committees, and management and could cause confusion to the user, lead to legal implications in terms of releasing confidential information and/or force management to include items within the financial statements that they otherwise would not have

included and which are not required to be disclosed under current requirements. When the auditor believes it is required to disclose confidential, sensitive company information that the company is not required to disclose and such disclosure would damage the company, contentious legal and relationship issues could arise between the company and the auditor. Relationships between issuers and auditors that contain healthy tension are to be desired; dysfunctional, adversarial relationships are not.

In addition to our concerns noted above, we also believe that CAMs as defined in the proposal are too broad and may lead to the auditor disclosing many CAMs thereby producing lengthy audit reports. Auditors will likely compile a comprehensive list of potential CAMs that would include items (1) documented in the engagement completion document, (2) reviewed by the engagement quality reviewer, (3) communicated to the audit committee, or (4) any combination of the three. The auditor would then need to determine which ones meet the definition of a CAM and would be included in the auditor's report. As part of their internal documentation, the auditor would need to justify why the matter is not considered a CAM. In applying this current PCAOB guidance, we are concerned that most auditors would err on the side of including more rather than fewer CAMs in their reports due to the fact that CAMs will be subject to second guessing by PCAOB inspectors. This could lead to lengthy discussion in the auditor's report causing confusion to the readers of the financial statements and distract from the primary purpose of the auditor's report. The CAM disclosure requirements would add to the "information overload" that is already a real concern with SEC disclosure documents today, as acknowledged in October by Mary Jo White, chairwoman of the SEC:

When disclosure gets to be 'too much' or strays from its core purpose, it could lead to what some have called 'information overload' — a phenomenon in which ever-increasing amounts of disclosure make it difficult for an investor to wade through the volume of information she receives to ferret out the information that is most relevant.¹

We are also concerned that if as part of the PCAOB inspection process the PCAOB felt that the auditor should have identified a matter as a CAM but did not, the auditor could be required to reissue their audit report, which would be concerning for the company impacted, the users and the auditor.

We believe that the costs associated with including CAMs in the auditor's report will be substantial due to the additional time required by the auditor to identify CAMs which would likely involve lengthy discussions with senior management on the audit team and could include consultation with the national office, in-house legal counsel, and others. In discussion with our auditors, they indicated that they expect that the process of identifying all potential CAMs will take a significant amount of time, which would translate to higher audit fees. In addition, significant indirect cost would likely be incurred by management in reviewing the CAMs and having discussions internally and with the auditor. We believe that the costs in terms of time and dollars to identify CAMs including the significant time the auditor would spend on justifying items that will ultimately not be reported to the public will add little, if any, value to the investors.

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¹ Speech to National Association of Corporate Directors, October 15, 2013.

We also have concerns regarding the strong wording of the PCAOB's definition of a CAM which indicates that an audit matter is a CAM if it "posed the most difficulty to the auditor in forming the opinion on the financial statements". Auditors will likely use this same verbiage in their reports to indicate why an issue was selected as a CAM. When a user reads that an issue posed difficulty to the auditor in forming the opinion on the financial statements, this could be interpreted by the user that the auditor is not comfortable with the issue being referenced. In addition, if this statement is made for some CAMs but not others, it may not be apparent to the user of the differentiating factors in disclosing this statement. This could cause a lot of confusion and raise questions about the auditor's conclusion even though the auditor was able to get comfortable with the matter and issued an unqualified opinion.

We also believe that over time the language within the audit report may become boilerplate which would undermine the PCAOB's goal of increasing the informational value of the auditor's report. The audit issues identified as CAMs would be the same from year to year. In addition, audit firms will likely try and standardize the types of language used across various companies for similar issues in an effort to mitigate legal liability and to minimize PCAOB inspection findings.

Due to the various concerns identified above, Lilly strongly opposes the PCAOB's proposal to require auditors to identify critical audit matters within the auditor's report. We believe that any perceived shortcoming in the information presented to investors and other users should be communicated by management through the footnotes or MD&A and not through the auditor's report. If necessary, the FASB or SEC should address concerns through developing or further enhancing financial reporting disclosures. However, if the PCAOB does move forward with this requirement we would ask that the PCAOB strongly consider the following enhancements to the guidance/definition of a CAM:

- a) An auditor must not be the original source of the information. The PCAOB should specifically clarify that if an issue is not required to be reported under current disclosure requirements then the matter should not be referenced by the auditor unless the company has elected to disclose this information.
- b) CAMs must be material to the financial statements.
- c) Highly sensitive (i.e. litigation, tax positions, etc.) and market or company confidential information should not be included as a CAM.
- d) CAMs should not include information that is specifically excluded from disclosure by other legislation (i.e. significant deficiencies, etc.).
- e) The audit report should not describe the audit procedures related to critical audit matters (we believe the examples in the Release are unclear and could lead audit firms to believe that such disclosures are required).
- f) Auditors should not be required to separately document why audit matters are not considered to be CAMs.

Proposed "Other Information" Standard

The PCAOB "other information" proposal would require the auditor to 'read and evaluate' the other information as opposed to the current requirements under AU 550 which only require the

auditor to 'read and consider' other information outside of the financial statements. The proposal specifically indicates that the auditor should evaluate the other information for a material misstatement of fact as well as for a material inconsistency with amounts or information, or the manner of their presentation, in the audited financial statements. In addition, the new proposal would expand the auditor's responsibility to include information incorporated by reference in the annual report including the proxy statement. Lilly generally supports the PCAOB proposal to clarify the auditor's current responsibilities under AU 550 and believe this information would be beneficial and help users to better understand the procedures being performed. However, we are concerned about the proposal to require the auditor to "evaluate" the other information which we believe could substantially increase the scope of the audit.

As stated above, the terminology change from "consider" to "evaluate" appears to represent a significant increase in the auditor responsibility for other information outside of the financial statements by introducing required audit procedures to support the auditor's conclusion about the auditor's evaluation of other information. We believe that this increase in scope would shift the auditor's focus away from the financial statements, negatively impacting audit quality and would lead to significant additional time and costs which would not be justified by the perceived benefits. The implementation of this proposal would lead companies to furnish periodic filings at an earlier stage of the process in order to allow the auditors to complete their procedures prior to the filing deadline. Doing so could put a severe strain on companies and auditors during the already tight reporting timelines and could delay of information being released to the public.

Due to the subjective nature of the information provided, it may be difficult for auditors to "evaluate" other information outside of the financial statements which includes non-financial data and information related to the company's operations. The MD&A provides historical and future business performance "through the eyes of management" and is intended to be qualitative and more forward-looking in nature. It could be very challenging for an auditor to "evaluate" qualitative statements for a "material misstatement of fact" and for consistency with the financial statements and relevant audit evidence. The guidance indicates that the auditor "would not be required to perform procedures to obtain additional audit evidence regarding other information not directly related to the financial statements that was not required to be obtained during the audit". However, we still have concerns that the auditor would need to expand their audit scope and procedures to fulfill their obligations to "evaluate" this type of information. The intent of this proposal is to further protect the interests of investors; however, this change could have the opposite effect as the information that management discusses in the MD&A may be influenced by the auditor or management may choose to limit the items they discuss in their MD&A to avoid issues with the auditor.

If this proposed requirement to evaluate the other information were implemented, the accounting firms would have to develop new methodology on their interpretation of the standard. This could lead to various discussions and questions as to how to interpret the standard and could lead to unintended consequences. For example, auditors would need to determine how differences in opinion or facts relating to other information would be compiled, evaluated and communicated to management and the audit committee. These differences could end up being reported in a manner that is similar to the summary of audit differences used in the financial statement audit which would give more weight to these items than what is necessary. Questions could also be raised as to whether management would need to develop controls around the MD&A and the

other information and if a difference was identified, it could lead to discussions around whether the difference would constitute a control failure. While these consequences may not be the intent of the proposal, these are just a few examples of how the audit firms may interpret the guidance in a manner that extends beyond the intent of the PCAOB. We urge the PCAOB to strongly consider the impact of these changes and how they may be interpreted by auditors to avoid a situation similar to what occurred with the implementation of AS2 in which auditors performed substantially more work than was intended causing the standard to be subsequently modified.

We are also concerned about the implications of expanding the definition of "other information" to include "information incorporated by reference from the company's definitive proxy statement". The deadline for the filing the proxy is 120 days after year-end; therefore this information is often not available to the auditor until after the issuance of the audit report. The guidance is unclear as to how the auditor would issue their audit report without first reviewing the proxy if they are required to "evaluate" the proxy as part of their opinion. We are concerned that companies may be forced to move up the filing of the proxy to align with the company's 10K filing date.

As stated above, we are supportive of clarifying the auditor's current responsibility under AU550 for other information outside of the financial statements which we believe will increase transparency and relevance to users without increasing the scope of the audit. However, we oppose the PCAOB's proposal to require the auditor to "evaluate" the other information for reasons discussed above. If the PCAOB elects to move forward with their proposal, we urge the PCAOB to field test the proposal first so that the implications of such a change can be properly assessed. In addition, we believe that the PCAOB should retain the section of AU 550 that specifically states that the auditor's responsibility "does not extend beyond the financial information identified in [the audit] report" and we urge the PCAOB to specifically exclude the auditor from responsibility for prospective financial data. We also oppose the PCAOB's proposal to expand the definition of "other information" to include information incorporated by reference from the proxy statement. We encourage the PCAOB to limit the auditor's responsibility to information available prior to issuance of the audit report.

Amendments to the Basic Elements of the Auditor's Report

The PCAOB release indicates that commenters on the PCAOB's concept release noted that modifications to the language used in the auditor's report could "improve financial statement users understanding of the nature of an audit, the auditor's responsibilities, and the purpose of the auditor's report." The Board has therefore proposed certain clarifications to existing language in the report to include statements about (1) auditor independence; (2) auditor tenure; (3) the auditor's responsibilities related to fraud and the financial statement footnotes; and (4) the auditor's responsibilities for, and the results of the auditor's evaluation of, other information. Below we discuss our view on each of the clarifications.

Lilly is generally supportive of the PCAOB's proposed enhancement to the basic elements of the auditor's report with the exception the proposal related to "Auditor Tenure". We understand that there is some investor interest in having visibility of auditor tenure. However, we believe that including this type of information within the audit report could be misleading to investors as there is no substantiated evidence to support that audit tenure has an impact on the quality of the

audit. The inclusion of this information could lead investors to infer that if the company has a new auditor or if a company and auditor have a longstanding relationship that the audit opinion is not as reliable. Auditor tenure is more appropriately considered a corporate governance matter and could easily be included in a company's proxy statement.

We are supportive of clarifying "Auditor Independence" within the auditor's report. We believe this could provide users with a better understanding of the auditor's role and provide more confidence in their judgments and process.

We are supportive of clarifying "Auditor's responsibility for fraud and the financial statement footnotes" within the auditor's report. We believe that including the auditor's responsibility for the detection of fraud within the standard auditor's report is more transparent to users. We are also supportive of revising the auditor's report to provide clarification on the auditor's responsibility for the financial statement footnotes that is consistent with the current auditing standard.

As discussed above within the "Proposed 'other information' Standard" section of this document, we are supportive of clarifying the auditor's current responsibilities under AU 550. We are supportive of the PCAOB's proposed language with the exception of the verbiage indicating that the auditor "read and evaluated" the other information. We believe that the PCAOB should retain the current requirements of AU 550 for the auditor to "read and consider" the other information. As such we would propose the following statement be included within the auditors report; "On the basis of relevant audit evidence obtained and conclusions reached during the audit we have read and considered the other information contained in this filing. We did not audit the other information and do not express an opinion on that information. Based on our review we have not identified a material inconsistency or material misstatement of fact in that information". We believe that the inclusion of this language would enhance the standard report by ensuring that the responsibility of the auditor related to the other information is clear to the financial statement users.

Clarifying auditor independence, auditor responsibility for fraud and footnotes and auditor responsibility for "other information", as outlined above, would not alter the scope of the audit nor impact the auditor's responsibilities; this would however provide additional information to users without changing the fundamental role of the auditor. We believe that these amendments to the basic elements of the auditor's report (with the exception of auditor tenure) most closely align 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 proposed changes to the basic elements of the auditor's report could 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 are very

concerned that requiring auditors to identify critical audit matters and expanding the auditor's responsibility for "other 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 these 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.

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) 651-2310.

Sincerely,

ELI LILLY AND COMPANY

/s/ Donald A. Zakrowski

Donald A. Zakrowski Vice President, Finance and Chief Accounting Officer