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Technical Director
File Reference No. 2015-330
Financial Accounting Standards Board
401 Merritt 7, P.O. Box 5116
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Dear Director,

Eli Lilly and Company ("Lilly" or "we") appreciates the opportunity to comment on the Financial Accounting Standards Board's (the "Board") Proposed Accounting Standards Update, "*Business Combinations (Topic 805) – Clarifying the Definition of a Business*" (the "Exposure Draft"). Lilly is a multinational pharmaceutical and animal health company. We manufacture and distribute our products through facilities in the United States, Puerto Rico, and 11 other countries, and our products are sold in approximately 120 countries.

Lilly supports the Board's objective to clarify the definition of a business. As a member of the life sciences industry, we frequently deal with the highly judgmental and complicated area of determining whether an acquisition, investment or in-license of a drug product or product candidate should be accounted for as a business combination or an asset acquisition. The determination of whether such transaction constitutes a business combination or an asset acquisition is very important as the accounting significantly differs between the two types.

The application of the current definition of a business to transactions in the life sciences industry can be challenging, particularly when the acquired set is in the development stage (e.g., the acquisition or in-license of a drug product candidate prior to regulatory approval for marketing). We agree with the Board's proposed amendment to include a screen to reduce the number of transactions that need to be evaluated and agree that an acquired set would not be considered a business when substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. We agree with the Board's proposed amendments that would require an acquired set to include, at a minimum, both an input and a substantive process that together contribute to the ability to create outputs. We also agree with the removal of the evaluation of whether a market participant could replace any of the missing elements of the acquired set. Lastly, we agree with the Board's proposal to narrow the definition of outputs to be consistent with how outputs are described in Topic 606. We would like to thank the Board for undertaking this project and we believe this clarification will further align the accounting better with the underlying economics of our transactions.

While we are supportive of the Board's objective to clarify the definition of a business, we believe that certain areas of the Exposure Draft require further clarification to assist companies and audit firms in its application. Our comments and suggested changes are incorporated into the following responses to selected questions in the Exposure Draft:

Question 1: Do you agree that to be a business a set of assets and activities must include, at a minimum, an input and a substantive process that together contribute to the ability to create outputs? If not, what other alternatives would you suggest?

We agree that to be considered a business a set of assets and activities must include, at a minimum, an input and substantive process that together contribute to the ability to create outputs. Clarifying that the process must be substantive is a significant improvement in the definition.

Question 2: Paragraphs 805-10-55-5A through 55-5D provide guidance on determining whether a set contains an input and a substantive process that together contribute to the ability to create outputs. Are the criteria appropriate, and would they be operable in practice? If not, why?

We believe that the criteria are appropriate and necessary to the application of the guidance in the Exposure Draft. However, we believe that the wording in the first sentence of paragraph 805-10-55-5A (as well as the similar wording in paragraph 805-10-55-5) should be changed to include the word "significantly" when referring to a set having both an input and substantive process that together contribute to the ability to create outputs, as follows:

"805-10-55-5A When a set does not have outputs (for example, an early stage company that has not generated revenues), the set would have both an input and a substantive process that together significantly contribute to the ability to create outputs if it includes an organized workforce that has the necessary skills, knowledge, or experience to perform an acquired process (or group of processes) that, when applied to another acquired input or inputs, is critical to the ability to develop or convert that acquired input or inputs into outputs."

We believe that the addition of the word "significantly" is critical to the application of the proposed guidance as any inputs and processes acquired could be perceived to contribute to the set's ability to produce outputs. The word "contribute" could be interpreted broadly and we believe that unless the inputs and substantive process significantly contribute to the ability to produce outputs, the acquired set would not meet the definition of a business.

We agree with the guidance in paragraph 805-10-55-5C that the continuation of revenues does not, on its own, indicate both an input and substantive process have been acquired, as it is possible for a company to continue to produce outputs without having acquired any substantive processes (through application of its own existing processes or by obtaining new processes after the close of a transaction).

Paragraph 805-10-55-5D requires that a company consider whether the service provided through a contractual arrangement represents either 1) an acquired process that is critical to the ability to create outputs (as this may indicate that the acquired set includes an organized workforce) or 2) an input. Pharmaceutical companies, like companies in other industries, often use contractual service arrangements. The most common in our industry that would be relevant to this analysis would be our use of contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") to assist in the development and/or commercialization of pharmaceutical compounds or molecules. While it seems that these arrangements would often meet the definition of an input (they give the company "the ability to obtain access to necessary materials or rights, and employees), the evaluation will involve judgment. A list of factors to consider in evaluating whether these contractual service arrangements represent an acquired process or an input would assist companies with the evaluation and reduce diversity in practice. These factors might include the length of the arrangement (presumably the shorter the arrangement, the less likely it is to represent an organized workforce) and the control the entity has over the personnel assigned by the service provider (presumably the more control the

entity has over the hiring, firing and the efforts to retain the personnel assigned to them, the greater the likelihood that the arrangement would represent an organized workforce). Another factor to consider might be whether the personnel performing the contractual service are merely executing pre-determined plans or if they have unique knowledge/expertise and decision-making authority to alter those plans.

Further, we are concerned that if the proposed guidance in the Exposure Draft does not include the suggested changes and clarifications related to evaluating contractual service arrangements, companies or audit firms could apply a broad interpretation of what constitutes a substantive process, and contractual service arrangements may be viewed as substantive processes when they are not. This broad interpretation would also have implications on applying the initial screen in paragraph 805-10-55-9A, as further described in our response to Question 4 below.

Question 3: Would the proposed guidance be operable without the criteria in paragraphs 805-10-55-5A through 55-5D? Why or why not?

We do not believe the proposed guidance would be operable without the criteria in paragraphs 805-10-55-5A through 55-5D as those paragraphs provide important guidance on evaluating whether an acquired set includes both an input and substantive process. However, we believe those paragraphs require additional clarifications, as described in our responses herein.

Question 4: Paragraph 805-10-55-9 provides that the presence of more than an insignificant amount of goodwill may be an indicator that an acquired process is substantive. Do you think this indicator is appropriate and operable? Why or why not?

We think this indicator is appropriate, but estimating the amount of goodwill may be challenging given the current proposed guidance in the Exposure Draft. Paragraphs 805-10-55-5A through 55-5B require an analysis of the processes acquired, including any contractual arrangements that take the place of employees, as they are described in paragraph 805-10-55-5D. Paragraph 805-10-55-5D requires that a company analyze contractual arrangements to determine if they represent an organized workforce. Presumably, the presence of an organized workforce could indicate that goodwill is present; however, this raises a valuation issue since the fair value of a service contract and the fair value of an organized workforce are valued differently.

This concept would complicate the operability of the initial screen in paragraph 805-10-55-9A. We believe the example in paragraph 805-10-55-56 where the at-market CRO and CMO contracts in the acquired set did not result in any fair value attributed to such contracts illustrates the Board's intent that the initial screen should be performed with the fair value of the contract determined as the off-market component of the service contract and should not be assessed as a workforce would be valued (which would typically be the "replacement cost" of the employee base). We urge the Board to provide language to clarify their intent on the valuation of these service contracts for purposes of conducting the initial screen. The guidance for the performance of the initial screen should indicate that regardless of whether or not a service contract is viewed as an organized workforce, the fair value of the service contract should be assessed/determined as the off-market component of the service contract.

We also believe that the proposed guidance in the Exposure Draft should include language that makes it clear that any goodwill generated by deferred taxes (for example, as a result of the purchase of the equity of an entity that includes only intellectual property) should be excluded in a company's analysis of whether there is more than an insignificant amount of goodwill. The analysis of whether there is more than an insignificant amount of goodwill should consider only goodwill generated by acquiring a process (for example, an organized workforce or other acquired processes).

Question 5: Do you agree with the changes proposed to the definition of outputs? That is, do you agree that for purposes of evaluating whether a transferred set is a business, outputs should be focused on goods and services provided to customers? If not, why?

We agree with the proposed changes to the definition of outputs and agree that outputs should be focused on the final goods or services provided to customers. However, we believe that the Exposure Draft should include a definition of "goods or services," "other revenues," and "customers" to provide clarity on what those are. For example, in the pharmaceutical industry, it is common for companies to sell or license pre-clinical or early phase assets (such as pharmaceutical compounds or molecules) to strategic or financial buyers who seek to further develop the asset. Such early phase asset is not considered a final "good" that generates revenues from sales to patients. Therefore, we would generally not consider the sale of such early phase asset the sale of a "good". And while some pharmaceutical companies may classify the consideration received from such a sale or license of an early phase asset as "other revenues" in their income statements, we believe that the consideration received from such sale or license should not be considered "other revenues" when evaluating the definition of an output. Lastly, in our industry we would not consider the buyer or licensee in such transaction a "customer", as we believe the customer should represent the final end-user of the final good/product (for example, the individual patients that purchase a regulatory approved drug, or the distributor who distributes the regulatory approved drug). It would be helpful if the standard provided clarification that the resale or out-license of the previously acquired asset (in our case, a drug in development), should not be considered an "output" if that is the intent.

While we agree that outputs should be focused on goods and services provided to customers, we do not believe the proposed changes to the definition of outputs is clear and may result in complexity in its application. We believe that it was the Board's intention to narrow the definition of outputs; however, without additional clarifications it may continue to be applied broadly to transactions involving early phase assets in the pharmaceutical industry.

Question 6: Paragraphs 805-10-55-9A through 55-9C specify that if substantially all the fair value of the gross assets acquired is concentrated in a single identifiable asset, the set is not a business. Is it appropriate to include such a threshold, and would it be operable? If not, why?

We agree that if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset, this indicates that the transaction represents the acquisition of an asset and the set is not a business. It is appropriate to include such a threshold and we agree that this screen should first be applied in evaluating whether a set constitutes a business. However, we are concerned that such threshold may be difficult to operationalize and apply to transactions without clarity that it may be appropriate in certain circumstances to use a qualitative approach to determine whether substantially all of the fair value is concentrated in a single asset.

Paragraph BC36 in the Exposure Draft's "Background Information and Basis for Conclusions" provides additional information on how a company may determine if substantially all of the fair value of the gross assets is concentrated in a single identifiable asset and infers that a company may be able to determine if the "substantially all" threshold has been met either quantitatively or qualitatively. However, BC36 goes on to state that an entity must determine the fair value of each asset to allocate the consideration to the assets recognized in both an asset acquisition and a business combination and they would "not expect any quantitative analysis to result in incremental costs or complexity." This is not the case in the pharmaceutical industry, particularly for a pre-regulatory approved pharmaceutical compound or molecule. It is typical in our industry for the consideration for these assets to include future milestones and royalties in addition to any upfront consideration paid. If the transaction is considered to be the acquisition of pre-approval intangible assets, we

do not need to determine the fair value of the assets as we are only required to expense the upfront consideration and no in-process research and development intangible assets are capitalized if there is no alternative future use.

We are concerned that without specific language in the standard clarifying that it is appropriate in certain circumstances to use a qualitative approach to evaluate whether or not the threshold has been hit, it may become a presumption in practice that we must do a quantitative analysis. This could require us to hire valuation experts, which would increase cost, complexity and the time required to complete the analysis. This risk is significant in today's environment where reasonable approaches may not be viewed by some parties as acceptable unless there are specific words in the standard that would allow this type of approach. Therefore, we believe that the proposed guidance in the Exposure Draft should include language that makes it clear a qualitative-only analysis would be preferred, or is at least allowable, in determining whether the "substantially all" threshold in paragraph 805-10-55-9A is met.

Question 7: The threshold in paragraph 805-10-55-9A also applies to a group of similar identifiable assets. Would the identification of a group of similar identifiable assets be operable? If not, why?

We believe the Exposure Draft should allow for aggregation of similar intangible assets if they relate to one pharmaceutical compound or molecule. For example, in the pharmaceutical industry, it is possible that one compound or molecule may be licensed or acquired in a transaction. If that compound or molecule is approved in one regulatory jurisdiction but has not received regulatory approval in other planned jurisdictions due to the different regulatory approval process and timeline in the worldwide jurisdictions that the compound or molecule may be targeted for approval, that single compound/molecule could result in multiple units of account that would not be allowed to be aggregated into a single unit of account under current guidance. We believe the Exposure Draft should be modified to allow such aggregation or purposes of analyzing the "substantially all' threshold in paragraph 805-10-55-9A. Without such change, the threshold in paragraph 805-10-55-9A may be difficult for pharmaceutical companies to meet in these situations, even when substantially all of the fair value of the gross assets acquired is concentrated in a single pharmaceutical compound or molecule, as is the case with most acquisitions or in-licenses of pre-regulatory approved drug product candidates.

Question 8: Will the proposed guidance reduce the cost and complexity of applying the definition of a business? Why or why not?

Yes, however, we are concerned that without the suggested changes and clarifications we have proposed in this response letter, there will continue to be significant cost and complexity in its application.

Question 9: How much time would be necessary to adopt the amendments in this proposed Update? Should early adoption be permitted? Would the amount of time needed to apply the proposed amendments by entities other than public business entities be different from the amount of time needed by public business entities?

The proposed amendments and the Board's overall objective to clarify the definition of a business represent a significant positive change to the current definition of a business in Topic 805 and will help simplify the determination of whether a transaction should be accounted for as a business combination or an asset acquisition, particularly for companies in the pharmaceutical industry. We believe that the adoption of amendments in the Exposure Draft would not take considerable time and urge the Board to allow early adoption immediately after a final standard is issued.

Question 10: Do you agree that the amendments in this proposed Update should be applied prospectively to any transaction that occurs on or after the date of adoption, and do you agree that there should be no explicit transition disclosure requirements? Why or why not?

We believe that the proposed amendments in the Exposure Draft should be allowed to be applied retrospectively as of the beginning of the fiscal year that a final standard is issued. As the proposed amendments represent significant positive change to the current definition of a business in Topic 805 and should, with the appropriate clarifications, accomplish the Board's objective of eliminating today's broad interpretations of the definition of a business, we believe companies should be allowed to apply the guidance to any transaction that occurred in the same fiscal year of issuance of the final standard, even if those transactions occurred prior to the issuance of the final standard. We agree that no explicit transition disclosures are needed as sufficient disclosure requirements already exist.

Question 11: Do the examples in paragraphs 805-10-55-51 through 55-88 clearly illustrate the application of the proposed guidance? Why or why not?

We believe that the examples in paragraphs 805-10-55-51 through 55-88 will clearly illustrate the application of the proposed guidance as long as the Board incorporates the changes and clarifications suggested throughout this comment letter.

Question 12: Do the changes to the Master Glossary create any unintended consequences?

The proposed amendments to the Master Glossary refer to paragraphs 805-10-55-3A through 55-6 and 805-10-55-8 through 55-9C to define what is considered a business. We believe that the definition of a business, as it is defined in paragraph 805-10-55-3A, is inconsistent with the definition of outputs in paragraph 805-10-55-4(c). The definition of outputs was modified to remove "the ability to provide a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants." The exposure draft explains that the current language around providing a return in the form of dividends, lower costs, or other economic benefits can contribute to broad interpretations of the definition of a business. We believe it is the Board's intention to eliminate such broad interpretations of the definition of a business. However, that same language has been added to the definition of a business in paragraph 805-10-55-3A. We propose the following changes to paragraph 805-10-55-3A to better align the definition of a business with the definition of outputs:

"805-10-55-3A A business is an integrated set of activities and assets that is capable of being conducted and managed for the purpose of providing a return as a result of creating outputs. ~~a return in the form of dividends, lower costs, or other economic benefits directly to investors or other owners, members, or participants.~~ To be considered a business, an integrated set must meet the requirements in paragraphs 805-10-55-4 through 55- 6 and 805-10-55-8 through 55-9C."

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Conclusion

Lilly once again supports the Board's objective to clarify the definition of a business. We urge the Board to consider the changes and suggested clarifications provided in this response letter. We appreciate the opportunity to express our view and comments regarding the Exposure Draft. 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