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Mr. Russell G. Golden
Chairman of Emerging Issues Task Force
Financial Accounting Standards Board
401 Merritt 7
Norwalk, Connecticut 06856-5116

Re: EITF Issue No. 09-2, *Research and Development Assets Acquired and Contingent Consideration Issued in an Asset Acquisition*

Dear Chairman Golden:

Eli Lilly and Company reviewed the Exposure Draft (ED) related to EITF Issue No. 09-2, *Research and Development Assets Acquired and Contingent Consideration Issued in an Asset Acquisition* that was issued by the FASB for public comment on September 30, 2009. We are writing this letter to provide responses to questions posed in the ED, and raise other concerns we have with this project. In this response, we have generally chosen to refer to the accounting literature using the original pronouncements rather than the new codification references.

While we have responded to your questions and raised other questions below, we would like to highlight our most significant concerns, which are:

- We are concerned about the due process used to address this issue.
- We don't believe the proposed updates to the accounting standards accomplish the stated objective.
- We question whether the research and development (R&D) items addressed in the ED should be capitalized.

Our biggest concern from a process standpoint is whether or not this is an issue that should be addressed by the EITF. According to the FASB website, "The mission of the EITF is to assist the FASB in improving financial reporting through the timely identification, discussion, and resolution of financial accounting issues within the framework of existing authoritative literature." This ED effectively supersedes existing authoritative literature (SFAS 2) and would change the current accounting for R&D projects acquired in an asset acquisition. We believe this issue does not align with the EITF's mission and should be a project taken on by the FASB. We believe that if this issue is going to be addressed, it should be addressed as part of a complete review of R&D accounting, rather than reviewing the accounting for R&D in a piecemeal manner.

We also have concerns that the changes proposed may actually be farther reaching than we originally contemplated and require more time to study than allowed with a short comment period that overlapped the third quarter reporting period for calendar year end companies. We originally believed that this EITF issue was intended to be focused on the acquisition of R&D projects in development; which would be drugs in development for our industry. However, as we read the actual words used in the ED, it appears that it would also apply to other assets used in R&D activities, possibly resulting in some significant

changes from our existing practices. We know that the staff has reached out to companies regarding the central focus of this issue, but we are concerned that this project is being rushed through without enough attention being given to some of the other issues and that there could be some unintended consequences if this ED is approved as drafted. Again, if this issue is going to be addressed, it would benefit from a broader consideration of R&D accounting in its entirety as a project of the full board. If the decision is to move forward with this as an EITF issue, we strongly believe that more time is needed to study the implications of the proposal.

The ED says this proposed accounting standards update is being issued to address the inconsistency that results from the current situation where the form of the transaction in which an entity acquires R&D assets (either an asset acquisition or a business combination) could result in a different accounting treatment. However, we don't believe that the changes proposed in the ED will accomplish this. The proposal creates new inconsistencies in the accounting for assets acquired as compared to assets created internally. Further, amounts capitalized under the proposal would differ from amounts capitalized in a business combination. In other words, differences will continue to exist in the accounting for R&D assets acquired in a business combination and R&D assets acquired in an asset acquisition, and it would create new differences compared to the accounting for internally developed R&D assets. To be clear, although we do not favor conforming the accounting for R&D assets acquired in an asset acquisition with those acquired in a business combination, we do not believe the proposal accomplishes its stated objective.

Our other significant concern is the requirement to capitalize these R&D projects. As we have communicated previously, we question the appropriateness of capitalizing these highly risky assets that are most likely to fail, especially R&D projects that have not yet started Phase III clinical testing.

These concerns are discussed in more detail below; in addition to other concerns and our answers to the questions you posed.

Question 1: Do you agree that the cost of acquired tangible and intangible research and development assets acquired in an asset acquisition should be capitalized, regardless of whether they have a future alternative use? Why or why not?

We do not believe that the cost of these assets acquired in an asset acquisition should be capitalized regardless of whether they have alternative future use. We have several concerns with capitalizing these assets. One is that we do not believe that it is appropriate to capitalize the cost of in-process R&D programs acquired until the technology is proven and has been approved by regulatory agencies, if required. This and other considerations are discussed further below.

We believe that accounting for in-process R&D programs acquired in an asset acquisition is covered by SFAS 2, *Accounting for Research and Development Costs*. We acknowledge that there are currently inconsistencies in accounting for R&D assets acquired in an asset acquisition and acquired in a business combination with the implementation of SFAS 141R, *Business Combinations*. However, we have significant concerns with accounting governing bodies reviewing the accounting for R&D activities on a piecemeal basis. As mentioned above, we believe that if this issue is going to be addressed, the appropriate accounting authoritative body, which we believe is the FASB, should reconsider all R&D accounting in conjunction with a full review of SFAS 2. We believe that the determination of the appropriate accounting for in-process R&D programs acquired in an asset acquisition cannot be made without a complete reconsideration of SFAS 2 and perhaps the conceptual definition of an asset as well.

Introduction of a Third Accounting Model

While we have a basic concern about addressing the accounting for R&D on a piecemeal basis, we also question whether the proposed changes in the rules accomplish the objective of addressing inconsistency in the accounting for R&D assets acquired in a business combination as compared to those acquired in an asset acquisition. The proposed rule change does require capitalization of the allocated cost of the R&D asset acquired; however, significant differences in the accounting models will continue to exist and some new differences will be created. For example:

- R&D assets acquired in a business combination are capitalized at estimated fair value while those capitalized in an asset acquisition will be capitalized initially at allocated cost. In our industry, drugs in development are often acquired for a relatively small up-front fee, with provisions for significant contingent consideration if the drug is successful. As a consequence, the amount initially capitalized in an asset acquisition will differ dramatically from estimated fair value. This essentially introduces a third model for R&D projects: those developed internally have costs expensed as incurred; those acquired in a business combination are capitalized at estimated fair value as of the acquisition date; and those acquired in an asset acquisition are capitalized at allocated cost subsequently adjusted for contingent consideration that is resolved, which will initially differ significantly from estimated fair value.
- Transaction costs will be capitalized for asset acquisitions, while they are expensed for R&D assets acquired in a business combination.

The high risk of drugs in development, as discussed further below, leads to the relatively small up-front payments in asset acquisitions in our industry. Companies acquiring the drugs in development are generally unwilling to pay the full fair value up-front because of the high risk. The difference between the relatively small up-front and the fair value of the drug in development is generally made up with contingent consideration.

In summary, as opposed to resolving an inconsistency, it appears that the proposed rule change would actually create a third model for accounting for R&D assets in development that differs from both SFAS 2 and SFAS 141R. We have concerns about whether this really represents an improvement in the accounting in this area. To be clear, we do not favor conforming the accounting for asset acquisitions to the accounting model used in business combinations, as this creates further inconsistencies with SFAS 2.

Uncertainty of Future Economic Benefit

As we have stated in previous comment letters on this topic, we continue to have significant concerns regarding the appropriateness of capitalizing assets that are as risky as these R&D projects. Statement of Financial Concepts 6 states, "Assets are probable future economic benefits obtained or controlled by a particular entity as a result of past transactions or events." Probable in this instance "refers to that which can reasonably be expected or believed on the basis of available evidence or logic but is neither certain nor proved." While we understand that the FASB considered Concept Statement 6 in the finalization of SFAS 141R, we still believe the question of whether or not these projects meet the definition of an asset in Concept Statement 6 should be given significant consideration for accounting for in-process R&D programs acquired in an asset acquisition. Many R&D activities that are being investigated have a low likelihood of future success. In short, we believe that consideration spent directly on in-process R&D programs should be viewed as costs and not assets.

While we agree that compounds in development have some value and that a purchaser of the asset may consider that value when negotiating the purchase, we do not believe that all acquired compounds under development meet the definition of an asset as defined by Concepts Statement 6. It may not be precisely

clear what percentage is implied in the definition of "probable" in Concepts Statement 6, but it is hard to imagine that anything with a less than 50% chance of ever being marketed could meet the definition of having "probable future economic benefits." Paragraph 175 of Concepts Statement 6 further states that, "Uncertainty about business and economic outcomes often clouds whether or not particular items that might be assets have the capacity to provide future economic benefits to the entity…, sometimes precluding their recognition as assets."

Specifically, it is generally recognized within the pharmaceutical industry that compounds entering the following testing phases in their R&D life cycle have the corresponding approximate probability of achieving commercialization based upon current industry averages:

Testing Phase	Probability of being approved for sale
Pre-clinical - lead molecule identification	5-10%
Phase I	10-15%
Phase II	20-25%
Phase III	60-70%

Therefore, based upon the average probability of being approved for sale for any in-process R&D program in the pre-clinical, Phase I or Phase II testing phases, we have difficulty believing that these programs would meet the definition of an asset. We note that in FIN 48, *Accounting for Uncertainty in Income Taxes,* the Board chose to set a recognition threshold of more likely than not for the recognition of certain tax assets, but that they have not set a similar threshold for recognition of acquired in-process R&D projects. This approach seems inconsistent as many of these in-process R&D projects that would be capitalized would not meet the recognition threshold for an asset in FIN 48.

In addition, the AICPA Practice Aid, *Assets Acquired in a Business Combination to Be Used in Research and Development Activities: A Focus on Software, Electronic Devices, and Pharmaceutical Industries*, provided a bright line for the pharmaceutical industry that **only** compounds that have achieved regulatory approval represent an asset that requires capitalization in an acquisition. The SEC, an observer of this Task Force, was very clear at that time that they did not believe pharmaceutical assets should be capitalized prior to regulatory approval because of their high risk. The AICPA Practice Aid also required that early stage pre-clinical compounds would not be included in the valuation of in-process R&D programs, as it was presumed that the fair value could not be computed with reasonable reliability. Instead, these early-stage compounds would be included in the determination of goodwill.

Usefulness to Users of Financial Statements

We also have concerns as to whether capitalizing R&D assets acquired in an asset acquisition provides decision-useful information. We have talked to some of the investment and rating agency analysts that follow Lilly and have been told that having these assets on the balance sheet will not change the way they evaluate us; either they will ignore these assets or the assets will be excluded from the metrics they use to evaluate us. With regard to the income statement, one analyst told us that when evaluating our performance they add back to earnings the immediate charge that we record for these assets using current rules and they would also add back the impairment charge in the future if this proposed rule is ultimately approved

Further, we are concerned about the investor confusion that would likely result from a requirement to capitalize R&D projects acquired in an asset acquisition. We believe that we will be required to discuss in our Management's Discussion and Analysis section the low likelihood that any of these in-process R&D programs will provide the company "future economic benefit." We believe investors will not

understand why we are capitalizing assets that we state are likely to be written off in the near future. We are also concerned about the potential exposure that may occur given the litigious nature of our society.

Impact on Accounting for Assets Consumed in R&D

We also have concerns that the proposal as written in the ED will actually have broader implications than we originally anticipated and that this could raise operational difficulties. We originally understood this project to be focused on requiring those in our industry to capitalize R&D projects purchased in an asset acquisition. As we reviewed the markups of the proposed changes to the accounting standards, we became concerned that the proposal would also lead to changes to our accounting for tangible assets **consumed in** the R&D process. For example, we may purchase materials for use in clinical trials. Under existing guidance, these tangible assets would be expensed as they are tangible assets used in R&D that have no alternative use. Under the proposal, we are concerned that we would be required to initially capitalize these and similar assets. This would cause operational issues for us as we would need to inventory these items, track them, and expense them at the time they are consumed in the R&D process. We question whether this is an improvement in financial reporting, and even if there is an argument that this is an improvement, we question whether it is worth the administrative effort.

In summary, while we believe in-process R&D programs acquired in an asset acquisition should be expensed and this issue should wait until all R&D related issues can be considered at once, if the Task Force concludes that in-process R&D programs should be capitalized in an asset acquisition, we would urge the Task Force to consider establishing some probability threshold for recognition of these assets. A threshold that would result in capitalization of R&D assets acquired that are in Phase III testing, and expensing pre-Phase III projects would seem to be reasonable.

Question 2: Do you agree that contingent payment arrangements in an asset acquisition should not be recognized at fair value unless those arrangements are derivatives?

Yes, we agree that contingent payment arrangements in an asset acquisition should not be recognized at fair value unless those arrangements are derivatives. We believe that following the SFAS 5 model results in an accounting model that better agrees with the substance of the transaction from a business standpoint. Acquirers are often unwilling to pay the entire fair value of the asset up-front because of the risks and uncertainties and, therefore, the parties often agree to a relatively small amount to be paid up-front with a significant amount of contingent consideration. If the asset ultimately proves that it has greater value, more consideration will be paid. We agree with the assumption in the asset acquisition model that amounts paid to acquire the asset should be considered part of the cost of the asset regardless of whether the amount was paid up-front or as part of the contingent consideration.

If the task force concludes that contingent payment arrangements in an asset acquisition should be recognized at fair value, we believe that it would be inappropriate to proceed on this issue without re-exposing the issue and clarifying that this consensus would apply to all asset acquisitions (not just the acquisition of R&D assets). This issue has always been discussed as an R&D issue and has not been widely followed by other industries that assumed they would not be affected.

Question 3: This proposed Update does not provide guidance for determining whether a contingent payment relates to future services or consideration for the asset required. Paragraph 805-10-55-25 provides guidance for determining whether payments made to the seller in a business combination after the acquisition date relate to the acquisition of the business or the performance of future services by the seller? Do you believe that additional guidance is necessary for assisting in making

this determination in an asset acquisition? If you believe additional guidance is necessary, please provide any factors that you believe should be considered in making this determination.

If the task force decides to require capitalization of the R&D assets acquired in an asset acquisition, we think the question of determining whether a contingent payment relates to future services or consideration for the asset required should be addressed by stating the principle (that the portion of the contingent consideration that represents additional payment for the asset should be capitalized) in the update to the literature and allowing companies to determine how best to apply the principle to their unique set of facts and circumstances. We believe it is better to focus on the principle rather than trying to refer to any guidance that may or may not fit well to the existing facts and circumstances.

While we are not recommending that additional guidance be provided, it is important to understand that there will be complexities if we must capitalize contingent payments that represent additional consideration for the asset acquired. In our industry, these arrangements can take many forms. Some are relatively simple and result in the acquisition of the asset with no further involvement of the seller. The accounting for these would not be difficult to determine because no additional services are provided. However, at the other end of the spectrum are arrangements under which the two parties will collaborate on both development and commercialization, with the parties contributing human resources, sharing all costs and profits. It may be very difficult to determine what a contingent payment is really paying for in this type of an arrangement. The seller is likely getting most of the reward for their efforts in this arrangement from the profit sharing, not the contingent consideration. It is very difficult to determine if the contingent consideration is for the asset, for services, or to offset other costs (e.g., R&D or marketing costs) that are to be incurred by the seller under the terms of the arrangement.

Other Issues

In addition to the questions posed in the ED, we do have some other questions/concerns, as discussed in the following paragraphs.

The proposed changes raise questions as to the appropriate amortization for certain intangible assets that are complete for their intended use, but are used in R&D activities. For example, we often acquire rights to intangible assets that are used in the development process for a variety of projects. We often refer to these as “tools” that may help speed the R&D process or help in identifying potential drugs. They are intangible assets acquired for use in R&D activities, but they are not the actual potential drug that we are attempting to develop. Pursuant to existing GAAP, we would (1) capitalize these intangibles because they have alternative future use, (2) consider these tools to have finite lives, generally the shorter of the contractual/legal life or the period in which we expect to use the tools, and (3) amortize them to R&D expense over that finite period. The ED appears to be written very broadly such that any intangible asset acquired for use in R&D activities shall be considered indefinite lived until the completion or abandonment of the associated R&D activities. It is not clear if this proposed guidance was intended to be applied to tools and, if it was, if using an indefinite life for these assets when they are utilized in R&D activities would result in an improvement over the current accounting. We also are unsure as to how to operationalize the accounting for this model. If this proposed guidance was not intended for intangible assets that are complete for their intended use, but are used in R&D activities, we recommend that you amend the proposed guidance to clarify this.

We do not understand why the ED contemplates striking paragraphs 730-10-05-2 and 730-10-05-3 as a part of this issue. It seems to us that these are general paragraphs discussing the rationale for accounting for R&D that apply to SFAS 2 and are still relevant. They do not appear to apply specifically to R&D assets acquired in an asset acquisition. We are concerned that the removal of these paragraphs now is not

only unnecessary, but also would remove from the literature some of the rationale supporting SFAS 2, which continues to be a part of the authoritative literature.

We also don't understand why the word "constructed" is proposed to be removed from the amended Subtopic 730-10. Our understanding is that this EITF issue is intended to focus on assets acquired in an asset acquisition and not those constructed by companies. It seems that removing the word "constructed" is unnecessary and could raise questions as to whether there was intent to change the accounting for constructed assets in addition to assets acquired. We recommend that you amend paragraph 730-10-25-1 to include, and therefore clarify, that assets constructed for research and development activities shall be charged to expense when incurred.

We appreciate your consideration of our views and concerns regarding the EITF Issue No. 09-2, *Research and Development Assets Acquired and Contingent Consideration Issued in an Asset Acquisition*. If you have any questions, or would like to discuss our comments further, please call me at (317) 276-2024.

Sincerely,

ELI LILLY AND COMPANY

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