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Technical Director
File Reference No. 2015-330
FASB
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P.O. Box 5116
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Subject: Proposed Accounting Standards Update (ASU), *Business Combinations (Topic 805) Clarifying the Definition of a Business (File Reference No. 2015-330)*

Dear Technical Director:

Pfizer Inc. is a research-based, global biopharmaceutical company headquartered in New York. We discover, develop, manufacture and market leading medicines and vaccines, as well as many of the world's best-known consumer healthcare products. In 2014, we reported revenues of \$50 billion and total assets of \$169 billion. While a significant portion of our research and development is done internally, we continue to seek to enhance our pipeline of potential future products by acquiring promising compounds in various stages of development. To ultimately bring such compounds to market as medicines, we must invest in additional research and development, which can be significant, prior to any submission for approval by the Federal Drug Administration or similar international regulator. Those compounds may be transferred as part of a legal entity that has no outputs.

Pfizer supports the Board's efforts to clarify the definition of a business. Our thoughts on the Exposure Draft are discussed in our responses to Questions for Respondents, below.

Questions for Respondents

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 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. We believe these minimum requirements provide a practical framework to distinguish between a business and an asset acquisition or disposal. Absent these minimum requirements, the definition of a business would be so broad as to potentially include many transactions that we believe are economically more in the nature of asset acquisitions or disposals, such as licensing and supply arrangements, or acquisition of a currently marketed brand coupled with a transitional supply agreement.

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?

Yes, the criteria are appropriate and, for the most part, would be operable in practice. However, we believe the guidance in paragraph 55-5D should be clarified and expanded on considering whether a contractual arrangement that takes the place of employees is itself an acquired input or rather, performs an acquired process applied to an input. When applying the guidance in paragraph 55-5D to paragraph 55-5A, we believe that the evaluation of whether or not the process is critical, or whether it is ancillary or minor, is important, but that the evaluation should also include the criteria in paragraph 55-5B, b. and c. That is, when considering whether a contractual arrangement for an acquired set that does not have outputs is performing a substantive process, the evaluation should consider 1) whether or not the process can be replaced without significant cost, effort, or delay, and 2) whether the process is considered unique or scarce.

In the pharmaceutical industry, companies may acquire early stage drug development companies in which a significant amount of the drug development work is performed by contract research organizations and the target company has a minimal workforce. We believe it would be helpful if the Board were to establish a framework that entities could use to determine whether a contract in lieu of an established, in-place workforce constitutes an input or a process. We also believe that in cases where application of the framework would lead to the conclusion that the contract constituted a process, we believe a list of indicators that a process is critical would be helpful. Also, an expanded illustrative example would ensure greater consistency in application of the guidance and minimize diversity in practice.

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. We believe that without the proposed criteria the definition of a business would be applied too broadly, undermining the intent of the proposed Update.

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?

Yes, the indicator is appropriate and operable, so long as it is sufficiently clear that it is only an indicator to assist in the evaluation of whether a substantive process is included in the acquired set. The Board may be able to clarify this further by incorporating some of the language from paragraph BC33 into paragraph 805-10-55-9.

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

In general, we agree with the proposed changes to the definition of outputs and the focus on goods and services provided to customers. We believe it is appropriate to incorporate other types of revenues into the definition since, as noted in the basis for conclusion, paragraph BC42, not all entities have revenues in the scope of Topic 606. For example, a biotech company may have income in the form of milestone payments or research payments from a collaborative arrangement with a collaboration partner (not from services provided to a customer). Also, the Board may wish to incorporate into the definition of outputs the notion of lowering costs, which has not been removed from the definition of a business.

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 are generally supportive of the proposed guidance specifying 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, and we believe it would be operable. We believe the assessment could be qualitative in many biotech acquisitions of a single asset company. However, in cases where there are multiple assets under development in the acquired set, the evaluation would be more complex.

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?

Yes. The identification of a group of similar assets would generally be operable. However, we would suggest that the paragraph 805-10-55-9B be further clarified by adding the guidance in the Basis For Conclusions, paragraph BC40, specifically that “an entity generally would be expected to use the same unit of account for evaluating the threshold as it would use for identifying assets recognized in a business combination.”

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

We do not expect the proposed guidance will reduce the cost and complexity of applying the definition of a business in most cases. While the “substantially all” threshold in paragraph 805-10-55-9A may reduce the amount of time to evaluate an acquisition of a pharmaceutical company with a single asset under development, considerable judgment will still be required when applying the guidance to other transactions. For example, in situations where significant judgment would be needed to determine whether the fair value applies to one, or a group of similar assets, as opposed to multiple assets, it may be necessary to perform a valuation to identify whether the transaction should be treated as an asset acquisition or a business combination.

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 Update could have a significant impact on future acquisitions within the pharmaceutical industry, particularly for acquisitions of small biotech companies with a single asset under development, which under current rules may qualify for business combination accounting, but under the proposed Update would be more likely to be treated as asset acquisitions. Given the stark differences in accounting for acquired in-process research and development assets in a business combination (capitalized as intangible asset) versus an asset acquisition (expensed in the income statement as R&D expense), and the difference in accounting for contingent consideration in a business combination versus an asset acquisition, companies in research-intensive industries will need sufficient time to adequately educate and train their Finance and Business Development groups so that they can plan and incorporate these impacts into their decision-making, budgeting and reporting processes. Also, investors will need time to educate themselves about how the changes will impact their assessment of those investments under the new

accounting rules. For these reasons, we would suggest an effective date of one year after issuance of the final Accounting Standards Update and that the date is at the beginning of the year so that all transactions are treated similarly.

Because the accounting treatment for asset purchases in research-intensive industries provides markedly different financial statement results than that for business combinations, Pfizer believes that to maintain comparability for financial statement users, early adoption of the proposed Update should not be permitted. We believe that having comparable financial statement reporting provides investors with more decision-useful information in cases where application of new accounting rules results in significantly different results than previously existing GAAP in the reporting of transactions and events.

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 have proposed several changes to the examples in the proposed Update to more clearly articulate principles explored in those examples, and to make certain editorial changes. We have attached a marked copy showing our proposed edits to the examples at the end of our letter.

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

There is one item we've identified thus far that could cause unintended consequences. That is the definition of the term "output" does not include lower costs, which is included in the definition of a business.

We appreciate the opportunity to provide our comments on the amendments in the proposed Update. We would be happy to discuss our comments with you further or to meet with you if it would be helpful.

Loretta Cangialosi

Loretta V. Cangialosi
Senior Vice President and Controller

cc: Frank D'Amelio
Executive Vice President and Chief Financial Officer

ATTACHMENT**Suggested Edits to Examples in the FASB's Proposed Accounting Standards Update (ASU), Business Combinations (Topic 805) Clarifying the Definition of a Business (File Reference No. 2015-330)****> > Case A: Acquisition of Single-Family Homes**

805-10-55-52 ABC acquires, renovates, leases, sells, and manages single-family residential homes. ABC acquires a portfolio of 10 single-family homes **in one residential neighborhood** that each have at-market in-place leases. **The market for leasing of homes in this neighborhood is strong with minimal effort necessary to replace tenants whose leases have ended and who have moved on to other properties.**¹

The only elements included in the acquired set are the 10 single-family homes and the 10 in-place leases. Each single-family home includes the land, building, and property improvements. Each home has a different floor plan, square footage, lot, and interior design.

805-10-55-53 ABC first considers the guidance in paragraph 805-10-55-9A and analyzes whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. ABC must first determine whether each single-family home would be considered a single asset for purposes of this analysis. ABC concludes that the land, building, and property improvements can be considered a single asset in accordance with paragraph 805-10-55-9B. That is, the building and property improvements are attached to the land and cannot be removed without incurring significant cost. However, the in-place lease is an intangible asset and cannot be combined with the tangible real estate in accordance with paragraph 805-10-55-9C.

805-10-55-54 ABC then considers whether the 10 tangible assets (the combined land, building, and property improvements) are similar. Each home is different; however, the nature of the assets (all single-family homes **in a single residential neighborhood with individual fair values within a reasonable range**) ~~are~~ **is** similar. As such, ABC concludes that the group of 10 single-family homes is a group of similar assets.

805-10-55-55 Next, ABC compares the fair value of the group of similar tangible assets with the fair value of the total gross assets acquired (the combined tangible assets plus the 10 in-place lease assets) and concludes that substantially all of the fair value of the gross assets acquired is concentrated in the group of similar tangible assets. That is, the in-place leases in this Example do not have significant fair value. As such, the set is not a business.

> > Case B: Acquisition of a Drug Candidate

805-10-55-56 Pharma Co. purchases from Biotech a legal entity that contains the rights to a Phase 3 compound being developed to treat diabetes (the in-process research and development project).

¹ We believe that the original description of the homes is too vague to illustrate the point about whether the homes can be a single asset. These additions attempt to make clearer the reason why the assets can be combined.

ATTACHMENT

Included in the in-process research and development project is the historical know-how, formula protocols, designs, and procedures expected to be needed to complete the related phase of testing. The legal entity also holds an at-market clinical research organization contract and an at-market clinical manufacturing organization contract. The clinical research organization contract provides services in which the vendor performs certain research and development activities that are part of the current phase of the research and development activities required by the U.S. Food and Drug Administration. The clinical manufacturing organization contract provides access to some of the necessary materials to perform those activities. **The services provided by the clinical research organization and clinical manufacturing organization are readily available from multiple third parties in the marketplace.**² No employees, other assets, or other activities are transferred.

805-10-55-57 Pharma Co. first considers the guidance in paragraph 805-10-55-9A and analyzes whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. Pharma Co. concludes that the in-process research and development project is an identifiable intangible asset that would be accounted for as a single asset in a business combination. Pharma Co. also concludes that there is no fair value associated with the clinical research organization contract and the clinical manufacturing organization contract **because these services are being provided at market rates, are not proprietary in nature and could be provided by multiple third parties in the marketplace.** Therefore, all of the consideration in the transaction would be allocated to the in-process research and development project. As such, **Big Pharma Co.** concludes that substantially all of the fair value of the gross assets acquired is concentrated in the single in-process research and development asset and the set is not a business.

>>> Case E: Acquisition of Biotech

805-10-55-67 Pharma Co. buys all of the outstanding shares of Target Biotech. Target Biotech's operations include research and development activities on several preclinical compounds that it is developing (in-process research and development projects). The set includes the scientists that have the necessary skills, knowledge, or experience to perform research and development activities. In addition, Target Biotech has long-lived tangible assets such as a corporate headquarters, a research lab, and testing equipment. Target Biotech does not yet have a marketable product and, therefore, has not generated revenues.

805-10-55-68 Pharma Co. first considers the guidance in paragraph 805-10-55-9A and analyzes whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. The identifiable assets in the set include multiple in-process research and development projects and tangible assets (the corporate headquarters, the research lab, and the lab equipment). In addition, Pharma Co. concludes that there is fair value associated with the acquired workforce **because of the proprietary knowledge of and experience with Biotech's ongoing development projects and the potential for creation of new development projects that the workforce**

² The language added to this example is to better illustrate why no fair value is assigned to the Contract Research Organization (CRO) and Contract Manufacturing Organizations (CMO) contracts, and as such, all the fair value is related to the IPR&D project.

ATTACHMENT

embodies. Pharma Co. also concludes that substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or group of similar identifiable assets. Furthermore, because of the significant amount of fair value associated with both the tangible assets and the acquired workforce, Pharma Co. does not assess whether the in-process research and development projects are similar (because even if those projects were similar, the threshold would not be met).

805-10-55-69 Because the set does not have outputs, Pharma Co. evaluates the criteria in paragraph 805-10-55-5A to determine whether the set has both an input and a substantive process. **Big Pharma Co.** concludes that the criteria in paragraph 805-10-55-5A are met because the scientists make up an organized workforce that has the necessary skills, knowledge, or experience to perform processes that, when applied to the in-process research and development inputs, is critical to the ability to develop those inputs into a good that can be provided to a customer. The presence of a more than insignificant amount of goodwill is another indicator that the workforce is performing a critical process. Thus, the set includes both inputs and substantive processes and is a business.

>>> **Case F: License of Distribution Rights**

805-10-55-70 Company A is a global producer of food and beverages. Company A enters into an agreement to license the Latin American distribution rights of Yogurt Brand F to Company B whereby Company B will be the exclusive distributor of Yogurt Brand F in Latin America. As part of the agreement, Company A transfers the existing customer contracts in Latin America to Company B. Companies A and B also enter into an at-market supply contract in which Company B will purchase all of Yogurt Brand F from Company A. Company A retains all of its manufacturing and distribution capabilities. That is, Company B does not acquire manufacturing inputs and processes or distribution inputs and processes (and does not have any of the intellectual property related to those processes or **the ability** to direct Company A's processes in any way) but only will purchase finished goods from Company A that it will sell and distribute to end customers in Latin America.