

August 11, 2014

Mr. Michael A. Mussallem  
Chairman and Chief Executive Officer  
Edwards Lifesciences Corporation  
655 15th Street, N.W.; Suite 385  
Washington, D.C. 20005

Dear Mr. Mussallem:

Thank you for appearing before the Subcommittee on Health on July 22, 2014, to testify at the hearing entitled “21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication.”

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on August 25, 2014. Your responses should be mailed to Jessica Wilkerson, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to [Jessica.wilkerson@mail.house.gov](mailto:Jessica.wilkerson@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

## **Attachment 1—Additional Questions for the Record**

### **The Honorable Joseph R. Pitts**

1. In your testimony, you note that the U.S. innovation ecosystem is eroding, can you elaborate as to what is contributing to this weakening? What actions should Congress take to reverse this trend? Based on your experience as an executive in the medical device industry, what do you think is essential to ensure we have a robust innovation ecosystem?
2. We've heard that the amount of data that has to be collected to gain U.S. regulatory approval and reimbursement is substantial. Can you give us an idea on how much clinical and economic evidence Edwards had to generate to obtain regulatory approval and reimbursement in the U.S.?
3. Based on your experience with an innovative medical technology, what improvements to the premarket approval process can be made from an evidence generation perspective?
4. As the sole manufacturer involved in the support and development of the TVT registry, what are the benefits of a registry?
5. There has been a lot of positive, supportive discussion regarding patient registries. Are there any risks or costs to them? What are they?
6. What guiding principles should be applied when deciding when and how to develop a registry?
7. Does the reimbursement system hold new, game-changing innovations to unrealistic evidentiary standards?
8. Has the FDA taken specific steps that have been enhanced evidence development mechanisms and how can they be improved? If so, what are they?
9. Have other countries created reimbursement incentives for innovation? If so, what are they and could you see them working here in the United States?

### **The Honorable Renee Ellmers**

1. Mr. Mussallem, in your testimony, you mention "reducing the legal complexity and inconsistency between each Institutional Review Board (IRB) through the creation of a centralized or standardized review process". In my district, I represent one of the largest clinical trial service providers, Quintiles. It is my understanding that without the use of a centralized IRB, clinical trials can be hindered because of the current excessive review process, where clinical trials are referred to many IRB's. What can be done to promote or help expedite the IRB review process?
2. Mr. Mussallem, as a committee, we've heard that the amount of data that has to be collected to gain U.S. regulatory approval and reimbursement is substantial. Can you give us an idea on how much clinical and economic evidence Edwards had to generate to obtain regulatory approval and reimbursement in the U.S.?