

August 11, 2014

Dr. Gregory F. Schimizzi
Co-Founder
Carolina Arthritis Associates, P.A.
1710 South 17th Street
Wilmington, N.C. 28401

Dear Dr. Schimizzi:

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.

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. Advances in data collection, recordkeeping and technology are helping to facilitate the development of tools and are presenting new opportunities to communicate truthful and non-misleading clinical information that will result in more precise clinical decision-making. It is important to note that when talking about "off-label" uses, it doesn't just refer to completely different indications of use, but also can include slight variances around the same indication that could include dosing, route of administration, subpopulations, previous therapies used by the patient, etc. Do you believe the current restrictions on off label communications are limiting health care professionals' ability to provide the most appropriate treatment to patients? If so, do you have recommendations on how to address these barriers?
2. While the goal of manufacturers is to run appropriate clinical studies that will enable FDA approved labeled indications, the reality is that it is impossible to accomplish this for all clinical variations due to a multitude of factors including limitations on clinical trial enrollment and cost. Manufacturers have access to robust data sets and information about their products for on and off-label uses. How can we find a way for patients and providers to have access to appropriate, material information about the product to ensure the best clinical treatment decision is made?
3. Are there examples of times when patients would have benefited from information about treatments outside of the PI?
4. Currently manufacturers cannot actively distribute any key information, even if it's related to the on-label indication, unless it is explicitly referenced in the package insert. You note that the information these companies have could be invaluable to practitioners, can you please explain further how having access to this information would benefit practitioners and patients?
5. What is the effect on physician practice when FDA makes it difficult for you to receive information and data from drug and medical device companies?
6. One component of the Alliance's position on Physician-Directed Applications is that if specialty physicians use a product for an indication not in the approved or cleared labeling, they have the responsibility to (1) be well informed about the product, (2) to base its use on a firm scientific rationale and sound medical evidence, and (3) to maintain awareness of the product's use and effects." How do physicians learn about these additional indications and what resources do they utilize to keep themselves informed and aware of the latest developments?