

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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August 13, 2013

Dr. David Gaugh, RPh
Vice President
Regulatory Sciences
Generic Pharmaceutical Association
777 Sixth Street, N.W., Suite 510
Washington, D.C. 20001

Dear Mr. Gaugh:

Thank you for appearing before the Subcommittee on Health on Tuesday, July 16, 2013, to testify at the hearing entitled "Reforming the Drug Compounding Regulatory Framework."

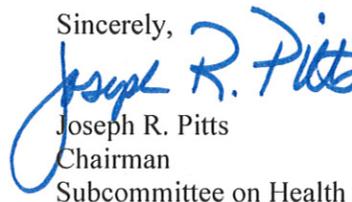
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose 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.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Tuesday, August 27, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@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

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Henry A. Waxman

1. AHSP has indicated that hospitals have come to rely on outsourcers to produce large amounts of certain specialized sterile products that are not commercially available. Can you explain what factors might have kept drug manufacturers from manufacturing these products? If outsourcers were unable or unwilling to make these specialized, non-commercially available products, do you believe your members would begin to do so?

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable John D. Dingell

1. Do you believe that it is important to have clear lines of division between FDA and State boards of pharmacy when it comes to regulating compounding pharmacies? Please elaborate.
2. Does Section 503(a), as currently drafted and interpreted, recognize the existence of these compounding outsourcers and our reliance on them? Please elaborate.