

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 6, 2014

Dr. Marcia G. Crosse
Director
Health Care
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Dr. Crosse:

Thank you for appearing before the Subcommittee on Health on Monday, February 10, 2014, to testify at the hearing entitled "Examining Drug Shortages and Recent Efforts to Address Them."

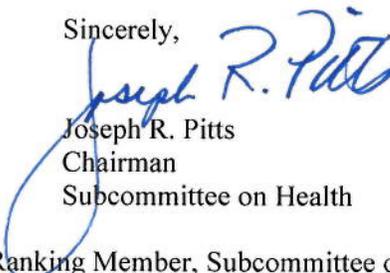
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose 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 with a transmittal letter by the close of business on Thursday, March 20, 2014. 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 Joseph R. Pitts

1. The FDA noted that you utilized different data in your study than the data the FDA uses to track drug shortages. Please explain why the different data does not detract from your study and findings.

The Honorable Henry A. Waxman

I understand that GAO analyzed drug shortage data compiled and maintained by the University of Utah Drug Information Service (UUDIS). The year-by-year drug shortage data reported by GAO differ somewhat from those reported by FDA. In order to better understand the significance of the differences, and in particular, how the differences may affect our understanding of the public health impacts of drug shortages, please answer the following questions.

1. Does the UUDIS shortage list include shortages that may present temporary problems for pharmacies but do not significantly affect the ability of patients to get access to the drugs they need? Does the FDA shortage list include such local shortages?
2. Can the UUDIS shortage list distinguish between shortages of medically important drugs (i.e., those that are life-saving, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition) and shortages of other drugs? What are the criteria by which a drug shortage is classified as critical? Can a shortage of a non-medically-important drug be listed as a critical shortage? Can a local shortage be listed as a critical shortage?
3. What is the basis by which a drug is removed from the shortage list? For example, do all the National Drug Code versions of a particular drug have to be restored by a manufacturer before the drug is removed from the shortage list? Will a drug remain on the drug shortage list if the drug is available from other manufacturers?
4. Does the UUDIS data enable GAO to distinguish between shortages that have been significantly mitigated and those for which there has been little or no mitigation? If not, would such distinction be useful in determining the relative effectiveness of efforts by FDA and industry to address shortages?

Thank you. I look forward to your responses in the next few weeks.

The Honorable Michael C. Burgess

1. In GAO-14-194, the GAO states that “there are shortcomings in its [FDA] management of drug shortage data that are inconsistent with internal control standards.” Would you elaborate on the shortcomings you referenced?

The Honorable Renee Ellmers

1. Section 1001 of the FDA Safety and Innovation Act require manufacturers to notify the Agency in instances when the manufacturer discontinues the production of a drug or if an interruption in drug production occurs. This provision of the law also empowers the Agency to issue a failure to notify letter if a manufacturer fails to comply. My understanding is that manufacturers are in good

compliance with this notification in FDASIA. Is that correct? Has the Agency been forced to use their failure to notify letter authority in statute?

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. Please submit a detailed response regarding how FDA could use its drug shortage database more proactively and whether the Agency needs more resources to implement the recommendations.

The Honorable Brett Guthrie

1. Please provide more detail about FDA's regulatory actions to prevent or mitigate drug shortages based on your discussions with Agency staff as well as manufacturers. Are FDA's actions or decisions being exercised consistently?