

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

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
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June 11, 2013

The Honorable Michele M. Leonhart  
Administrator  
Drug Enforcement Administration  
U.S. Department of Justice  
8701 Morrisette Drive  
Springfield, VA 22152-1080

Dear Administrator Leonhart:

Last year, we enacted provisions in the Food and Drug Administration Safety and Innovation Act (P.L. 112-144) to improve the predictability, consistency and transparency of the Food and Drug Administration's (FDA or Agency) prescription drug review process.

As you know, the Drug Enforcement Administration (DEA) also plays an important part in the review of prescription drugs containing controlled substances, including the predictability, consistency and transparency of that process, through its scheduling determinations. This DEA scheduling determination process can take up to six months and, in some instances, lag even longer. Such a delay in the review process means a lag in patient access to innovative treatments. In order for us to better understand the DEA review process and ensure that it is predictable, consistent and transparent, we ask you to provide answers to the following questions:

1. For each year from 2007 through 2012, how many substances contained in FDA-approved prescription drugs has the DEA reviewed and how long has each scheduling process taken once the DEA receives the FDA's recommendation?
2. Has the DEA ever deviated from the FDA's scheduling recommendation?
3. Has the average time for the DEA to schedule a substance used in an FDA-approved prescription drug increased, decreased, or remained the same between 2007 and 2012?

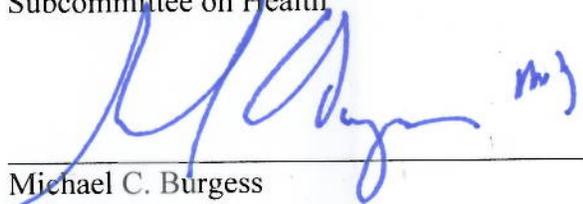
4. For substances that do not receive a final scheduling determination within six months, are there common reasons for delay? What steps, including discussions with the sponsor, does the agency take to address remaining outstanding questions when the scheduling process exceeds six months?

We stand ready to work with you to ensure the DEA's process of scheduling new prescription drugs both protects against the threat of abuse and provides patients timely access to new medications. If you have any questions regarding this letter, please contact Paul Edattel or Carly McWilliams with the Majority staff at (202) 225-2927. We kindly ask that you respond to the questions posed by June 26, 2013.

Sincerely,

  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

  
Marsha Blackburn  
Vice Chairman

  
Michael C. Burgess  
Vice Chairman  
Subcommittee on Health

  
Mike Rogers  
Member  
Energy and Commerce Committee

  
Phil Gingrey  
Member  
Energy and Commerce Committee

  
Renee Ellmers  
Member  
Energy and Commerce Committee

  
Bill Cassidy  
Member  
Energy and Commerce Committee

  
Leonard Lance  
Member  
Energy and Commerce Committee

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cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Frank Pallone Jr., Ranking Member