

**Congress of the United States**  
**House of Representatives**  
**Washington, D.C. 20515**

January 17, 2012

Angus Russell  
Chief Executive Officer  
Shire Pharmaceuticals  
725 Chesterbrook Boulevard  
Wayne, PA 19087

Dear Mr. Russell:

We are writing regarding recent reports of shortages of the generic version of the attention deficit disorder (ADD) drug Adderall XR. According to a recent report in the *New York Times*, these shortages are “widespread.”<sup>1</sup> The American Academy of Child and Adolescent Psychiatry calls them “devastating.”<sup>2</sup>

Shire manufactures both the brand-name and generic version of Adderall XR. In the *New York Times* report, some observers asserted that your company might be manipulating the market for this drug, taking advantage of the Drug Enforcement Administration (DEA) quota system to create an artificial shortage of the generic version of the drug and force patients to purchase the more expensive brand-name version.

To prevent abuse of drugs like Adderall XR, DEA has established a quota system to ensure that production is limited to the quantity of the drug that is expected to be used for legitimate medical purposes. Each manufacturer requests and receives an allotment of the drug that they can sell; DEA establishes this quota based primarily on sales from the previous year. Once they receive their quota, manufacturers can use it as they see fit.

According to the *New York Times*, your company has used your quota primarily for the brand-name version, “ensuring that supplies of branded drugs are adequate while allowing generic versions to go wanting.”<sup>3</sup> The effect of this policy could be to force consumers who need Adderall XR to pay for an expensive brand-name product rather than a less expensive generic drug.

DEA confirms that this may be happening, stating that “[a]ny shortage of these products is ... a result of decisions made by industry regarding manufacturing or distribution.”<sup>4</sup>

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<sup>1</sup> New York Times, *FDA Finds Short Supply of Attention Deficit Drugs* (Jan. 3, 2012).

<sup>2</sup> New York Times, *FDA Finds Short Supply of Attention Deficit Drugs* (Jan. 3, 2012).

<sup>3</sup> *Id.*

<sup>4</sup> Reuters, *Adderall Drug Shortage Will Continue in 2012, Government Officials Say* (Jan. 3, 2012)..

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We would be concerned if Shire were taking action to create a shortage of a critical generic drug. To help us understand this issue, we ask that you provide the following information and your company's actions and their impact on patients and taxpayers:

1. Shire's total DEA-allowed manufacturing quota for Adderall XR and its generic substitutes, for each year since 2007.
2. A detailed breakdown, by year, of production by drug and dosage form of Adderall XR and its generic substitute for each year since 2007.
3. The Wholesale Acquisition Cost for Adderall XR and its generic substitute, for each year since 2007.
4. The per-unit average and total reimbursements under the Medicaid program by drug and dosage form for Adderall XR and its generic substitute for each year since 2007.
5. Copies of all internal company documents describing Shire policies on production of Adderall XR and its generic substitute under DEA quotas.

We look forward to your response by January 31, 2012. If you have any questions regarding this request, please contact Eric Flamm or Brian Cohen on the Committee on Energy and Commerce staff, at 202-225-3641.

Sincerely,



Henry A. Waxman  
Ranking Member  
Committee on Energy  
and Commerce



Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations,  
Committee on Energy  
and Commerce



Frank Pallone, Jr.  
Ranking Member  
Subcommittee on Health,  
Committee on Energy  
and Commerce



Chris Van Hollen  
Ranking Member  
Committee on the Budget

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cc: The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce

The Honorable Cliff Stearns  
Chairman  
Subcommittee on Oversight and Investigations,  
Committee on Energy and Commerce

The Honorable Joseph Pitts  
Chairman  
Subcommittee on Health,  
Committee on Energy and Commerce

The Honorable Paul Ryan  
Chairman  
Committee on the Budget