



**Pharmacy  
Student Forum**

## **Legislative Letter Writing Toolkit**

*Policy and Legislative Advocacy Advisory Group 2012-2013*

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## INTRODUCTION

Dear Pharmacy Professional,

There is a saying that “politics precede policy,” and whether we want it or not, we know it is a true statement. Before a policy is created and goes into effect, before a bill becomes a law, there usually exists much discussion and deliberation about the specific provisions of the measure at hand. As much as we would want for the resultant laws to be effective and fair to all of the stakeholders affected by the provisions of the law, this is not always the case. As active members of the healthcare team, pharmacists need to take a proactive approach in the legislative process in our democratic society. It is important to remember that our system of government is based upon participation, those who make noise are generally heard. Conversely, silence is often viewed as acceptance. Pharmacists and pharmacy students alike, need to take an active role in informing their elected officials about the appropriate measures that are essential to improve health care. This is achieved through improved utilization of skills and services pharmacists can provide to the patients.

One can communicate with elected officials through various viable means; phone calls, personal visits, sending letters electronically, or via mail. However, many individuals do not utilize these opportunities due to the underestimation of the impact a simple letter, phone call, or visit can make. At the same time, those who see and seize the opportunities to make their voice heard by contacting their senators or representatives are successful with expressing their feelings. Submitting a document, as fundamental as a letter, can make a difference in the legislative decision-making process.

This toolkit was designed to serve as a resource to help students initiate an effective letter writing campaign to support the pharmacy profession. Provided is a sample letter outline, which can be applied to any pertinent issue. In addition, the background summary on the Prescription Drug User Fee Act (PDUFA) and the sample letter of support for PDUFA, provide examples of how to utilize the letter outline. This allows students with a means to create an effective letter based on a description of an issue pertinent to pharmacy. Best of luck!

## SAMPLE LETTER OUTLINE

[Your Name]  
[Address]  
[City, State, Zip]

[DATE]

The Honorable [Legislator Name]  
[Governing Body, ex. United States Senate]  
[Office Address]  
[Office City, State, Zip]

**Re: [Brief statement of what you want the legislator to do. Ex. Pledge to vote for H.R. 1234]**

Dear [Representative/Senator] [Legislator Last Name],

I am a pharmacy student at [School Name]. I am writing to ask you to [clear statement of what you want the legislator to do. Ex. vote for H.R. 1234.] As a constituent of yours, I hope that you will consider [support or standing against the issue].

[Explain the issue and how it impacts patients and the healthcare system. Consider including stories from your personal experience to give your letter more impact. Remember to be concise. Legislators are busy and a concise letter with a few well thought out points will be more effective than a long letter that includes every reason you have to support or not support the issue. See the ASHP Advocacy Toolkit for talking points for current pharmacy issues.]

I appreciate your time and consideration of this issue. I invite you to contact me with any questions you may have about the role that pharmacists can play in improving patient care.

Sincerely,  
[Your Name]  
[Title]  
[Organization]

## BACKGROUND SUMMARY ON THE PRESCRIPTION DRUG USER FEE ACT (PDUFA)

### Dealing with Drug Shortages - Prescription Drug User Fee Act (PDUFA) V

Enacted in 1992, the Prescription Drug User Fee Act (PDUFA) authorized the U.S. Food and Drug Administration (FDA) to require pharmaceutical manufacturers to pay a fee for an expedited review of a new drug application or a biologics license application. It has since been reauthorized 5 times at five-year intervals as part of the FDA Amendment Act. With every reauthorization, the act was amended to include new provisions. Throughout this time, the ASHP has taken an active advocacy position to ensure the new mandates were not unduly burdensome to pharmacists<sup>(1, 2)</sup>.

The most recent reauthorization of PDUFA was enacted on July 9, 2012, as the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. Thanks in part to the advocacy work done by the ASHP, PDUFA V includes provisions that provide the FDA with tools to better manage shortages of life-saving medications<sup>(2, 3)</sup>. Title IX of PDUFA V (S. 3187/H.R. 5651) includes the following key provisions:

- a. A manufacturer of a drug that is life-sustaining, life-supporting, or intended for the prevention or treatment of debilitating disease is required to report discontinuance or significant interruption of manufacturing of the drug to the FDA. The notice should be made 6 month prior to the discontinuance or significant interruption, or as early as practicable.
- b. The FDA will distribute this information to affected stakeholders, such as health providers, physicians, and patient organizations.
- c. The FDA will maintain an updated list of all drugs determined to be in short supply in the United States, along with the reasons for the shortages, and make the list publicly available.
- d. An expedited review process of major manufacturing changes to address potential and verified drug shortages.
- e. Annual report on drug shortages to be given to certain House or Representatives and Senate committees by the Secretary of the Health and Human Services and the Attorney General.
- f. Hospital repackaging of drugs in shortage in order to extend the supply of the drug and facilitate the access to the drug to hospitals within the same health system<sup>(3)</sup>.

Overall, the legislation requires manufacturers to report production disruptions that may result in a drug shortage, and provides the Department of Health and Human Services and the FDA with better means of strategically dealing with the shortages. ASHP believes that advanced notice of a drug shortage, reason for the shortage, and estimated duration of the shortage will assist healthcare providers in adequately responding to patient needs. Furthermore, this information will be utilized to prevent patient harm and minimize disruptions in care caused by drug shortages<sup>(1)</sup>.

Over the past year, ASHP has been actively advocating for the adoption of this bill and keeping the language to address and hopefully prevent drug shortages in the future. ASHP has also encouraged grassroots advocacy to support S. 3187/H.R. 5651 among the SSHPs nationwide. The following is a sample letter of support for PDUFA V developed by applying the skeleton letter this issue.

## SAMPLE LETTER

John Student  
123 Pharmacy Lane  
Durham, NC 27707

November 26, 2012

The Honorable Richard Burr  
United States Senate  
217 Russell Senate Office Building  
Washington, DC 20510

**Re: Pledge to vote for Title IX of PDUFA V (S. 3187/H.R. 5651)**

Dear Senator Burr,

I am a pharmacy student at UNC Eshelman School of Pharmacy. I am writing to ask you to vote for Title IX of PDUFA V (S. 3187/H.R. 5651). As a constituent of yours, I hope that you will consider supporting provisions under PDUFA V that will allow the FDA to better manage drug shortages of life-saving medications.

Drug shortages in hospitals and health-systems have been increasing at an alarming rate. Many drugs affected by shortages are life-saving cancer treatments as well as medications used to relieve pain, treat serious infections, balance electrolytes and other conditions. While some medications have therapeutic alternatives, those alternatives may be older products that have more side effects or a higher risk for adverse reactions. Many medications may not have a therapeutic alternative that is appropriate for each patient. I have personally witnessed the effects that drug shortages have on patient care. Drug shortages are resulting in delayed patient care, decreased quality of care, and increased patient safety concerns.

Title IX of PDUFA V would allow the FDA to better manage drug shortages. By requiring advanced notice of anticipated manufacturing shortages, hospitals and prescribers can plan in advance strategies to minimize disruptions in care. Title IX also includes provisions to help the FDA and hospitals respond to drug shortages and increase medication supply.

I appreciate your time and consideration of this issue. I invite you to contact me with any questions you may have about the role that pharmacists can play in improving patient care.

Sincerely,  
John Student  
PharmD Candidate, Class of 2013  
UNC Eshelman School of Pharmacy

## REFERENCES

- 1) ASHP Policy Positions 2009 – 2012, Policy 1118, Drug Product Shortages  
<http://www.ashp.org/DocLibrary/BestPractices/GovPositions.aspx>
- 2) Lisa Daigle, ASHP Policy Analyst. *PDUFA IV Strengthens FDA Oversight, Increases Drug Safety; Additional Drug User Fees Help Finance Expanded Authority*. September 2008.  
<http://www.ashp.org/DocLibrary/Advocacy/PDUFAIVFDAOversight.aspx>
- 3) United States. Cong. House of Representatives. *Food and Drug Administration Reform Act of 2012*. 112<sup>th</sup> Cong., 2<sup>nd</sup> sess. HR 5651. Washington D.C. 2012. <http://thomas.loc.gov/cgi-bin/query/z?c112:H.R.5651>: