

House Oversight and Government Reform Subcommittee
on Health Care, District of Columbia, Census and the
National Archives

Hearing on

Drug Shortage Crisis: Lives are in the Balance

November 29, 2011

Statement for the Record

Submitted by:



pharmacists advancing healthcare®

American Society of Health-System Pharmacists

7272 Wisconsin Avenue

Bethesda, MD 20814

Email: gad@ashp.org

Phone: 301-664-8710

Good morning and thank you Chairman Gowdy, Ranking Member Davis, and distinguished Members of the Subcommittee, for holding this hearing. My name is Kasey Thompson and I am Vice President of Policy, Planning and Communications for the American Society of Health-System Pharmacists (ASHP). I am here today to talk about the problem of drug shortages and the impact shortages are having on the ability of healthcare providers to care for our patients.

For the last 10 years, ASHP, in collaboration with the University of Utah drug information program, has been tracking and studying drug shortages, and making that information available to the public on our Web site. Since that time we have seen the number of shortages increase, almost tripling since 2006. As a result, hospital pharmacists and other healthcare providers have had to go to heroic lengths to find needed medications, spending time tracking down the product, rather than caring for patients. In some cases, we are told why there is a shortage, for example, there may be a quality issue with the production of the product, in other cases, we simply have no idea. Our analysis of shortages over the last 10 years has shown that most drug shortages are the result of quality issues in the manufacturing process, however, we recognize that there is no one cause of this problem, nor is there one solution. For example it has been suggested that Medicare reimbursement policies may be partially to blame for drug shortages. While we believe this is an area that should be explored further, we do not currently have the data to confirm that this is the case. We do know that drug shortages are not confined to oncology medications. Other significant shortages affect anesthesia, pain management, and nutritional support medications. These other drug classes have experienced increases since 2006 as well. This suggests multiple reasons for drug shortages, both quality assurance and

economic. We are pleased, however, to see that other facets of drug shortages, including economic factors, are being considered, but would warn against rushing to any conclusions given the limited data. It would be important to learn from other stakeholders in the supply chain in order to fully assess these causes and solutions to this public health crisis.

Fortunately, the Food and Drug Administration has been able to take steps to address drug shortages when they had access to certain information from drug manufacturers. For example, in 2010 FDA was able to prevent 38 shortages when drug manufacturers notified the agency when a product was discontinued or a manufacturing problem occurred. That number has increased to 101 shortages averted for 2011. For this reason, ASHP supports legislation in both the House and Senate that would require manufacturers to confidentially notify the agency when they experience production problems or discontinue a product. We know that confidential notification by drug manufacturers to the FDA is not a complete solution, nor does it prevent shortages from occurring, but it is a proven solution based on FDA's experience that can be implemented immediately while we look to examine other potential contributory causes of drug shortages.

Hospital and health-system pharmacists have been collaborating with other clinicians and members of the supply chain to work with FDA to address the problem. For example, we believe FDA should have and dedicate the necessary resources to speed up the regulatory processes that help resolve drug shortages. Other alternatives include improved communication between FDA field personnel and the drug shortages program to assess the

comparative risk of public harm when a potential enforcement action will cause or worsen a drug shortage; exploring incentives for manufacturers to continue or re-enter the market; a generic user fee program to speed approvals; and last, ensuring the agency has the funding it needs to carry out its mission.

In conclusion, drug shortages continue to be a very serious public health threat, not just for oncologics, but also for pain medications, anesthesia drugs, and nutritional products. While some causes are known, others are not quite as clear. ASHP supports more examination of these other factors to help identify additional causes of drug shortages currently plaguing our health care system. Again, thank you Mr. Chairman, ranking member, and all members of the committee for the opportunity to provide input on this urgent public health crisis