

ONE HUNDRED TWELFTH CONGRESS
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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Hearing on “Examining the Increase in Drug Shortages”
Subcommittee on Health
September 23, 2011

Thank you, Chairman Pitts, for holding this important hearing today.

Recent media and other reports indicate that drug shortages are now at an unprecedented level. Indeed, according to FDA, the number of drugs in short supply in 2010 was almost triple that of 2005. The shortages affect a broad spectrum of critically important drugs, including oncology drugs to treat lymphoma, leukemia, breast and other cancers; anesthesia drugs, without which surgeries have to be postponed; and antibiotics to remedy life-threatening bacterial infections. Without these drugs, patients’ lives are at risk.

Drug scarcities generally affect sterile injectable drugs. These drugs are technically difficult to make and each drug is usually manufactured by only one or a handful of producers. If any one company develops manufacturing problems -- which is not uncommon -- other companies may have little excess capacity to help fill the need.

With the aging of our population, the outsourcing of drug manufacturing, the increasing consolidation of drug companies, and the general adoption of a “just-in-time” approach to drug production and distribution, this problem may become significantly worse unless immediate measures -- including Congressional action -- are taken to address its multiple causes.

Rep. DeGette has introduced legislation that would be an important first step in this process. H.R. 2245, the Preserving Access to Life-Saving Medications Act of 2011, would require manufacturers to notify FDA of any actual or prospective drug shortages. Such advance notice would enable FDA to help avoid or mitigate the shortage, by both working with manufacturers and alerting hospitals and physicians of the problem.

While this is an important piece of legislation that has broad bipartisan support, I don’t think anyone believes it alone can solve the drug shortage problem. So I look forward to hearing from our witnesses today to better understand the causes of what is already a crisis for many patients and to find out what we in Congress can do to help prevent shortages in the future.

We already have been working in a bipartisan manner to learn about this very disturbing issue. I trust that we will continue to work together to develop and enact legislation to help address it and address it quickly.