

**Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Hearing on “Examining Drug Shortages and Recent Efforts to Address Them”
Subcommittee on Health
February 10, 2014**

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

Drug shortages are a continuing problem. The Committee has tackled this issue in a bipartisan manner, and I am confident that we shall continue to do so.

Since our last hearings on this topic two years ago, Congress passed bipartisan legislation addressing drug shortages, the FDA Safety and Innovation Act (FDASIA).

FDASIA requires companies to notify FDA six months before discontinuing the manufacture of a medically important drug. It also requires companies to notify FDA of meaningful disruptions in the manufacture of such a drug.

It requires GAO to issue a report on the causes of drug shortages and to make recommendations on how to prevent and alleviate such shortages.

And it requires FDA to maintain an up-to-date list of drugs that are in shortage, to develop a strategic plan for preventing and mitigating drug shortages, and to publish a regulation defining certain terms used to determine whether a drug is subject to notification.

FDA has the authority to subject biological products, such as vaccines, to the notification requirement if this would benefit public health. I was gratified to see in the draft regulation that FDA intends to make biological products subject to notification.

These were all important steps. However, we knew when we passed the legislation that it would not be a cure-all. And as we will hear today, it has not been.

The good news is that FDA has been able to prevent hundreds of shortages with its new authorities. The number of new shortages that began in 2012 was lower than the number that began in 2011, and the number of new shortages that began in 2013 appears to be lower than those that began in 2012. The bad news is that shortages continue to be a significant public health problem.

For example, a recent survey found that roughly 60% of pediatric hematologists and oncologists have had to alter therapies in response to drug shortages. Neonatologists continue to face shortages of ingredients for life-saving total parenteral nutrition for babies who cannot yet eat and have no other source of nutrition.

Shortages affect a broad spectrum of critically important drugs, including oncology drugs to treat lymphoma, leukemia, and breast and other cancers; anesthesia drugs, without which

surgeries have to be postponed; antibiotics to remedy life-threatening bacterial infections; and vaccines to prevent disease. Without these drugs, patients' lives are at risk.

According to the GAO report, about 60% of drug shortages are of sterile injectable drugs. These drugs are technically difficult to make and each drug is usually manufactured by only one or a handful of companies. If any one company develops manufacturing problems -- which is not uncommon -- other companies may have little excess capacity to help fill the need. These problems can be magnified when sterile injectable drugs are manufactured in aging facilities by generic drug companies whose low profit margins make it difficult for them to invest in upgrading their plants.

But the shortages are not limited to generic drugs. GAO reports that more than a quarter of sterile injectable drug shortages were of brand drugs not available as generics. And about a third of oral drugs in shortage are brand drugs not available as generics. We need to understand what is causing these shortages.

I want to thank FDA and GAO for being here, and look forward to their testimony.