

**Opening Statement of the Honorable Fred Upton**  
**Subcommittee on Health**  
**Hearing on “Examining Drug Shortages and Recent Efforts to Address Them”**  
**February 10, 2014**

*(As Prepared for Delivery)*

Thank you for holding today’s hearing on drug shortages - the first hearing we have held on this significant, ongoing public health threat since passage of the bipartisan Food and Drug Administration Safety and Innovation Act (FDASIA). This breakthrough agreement last Congress provided FDA with important new authorities and responsibilities to help prevent and mitigate drug shortages. I am eager to hear how they have been utilized and what measures can be taken to ensure doctors have access to every necessary treatment to care for their patients.

As required by FDASIA, FDA submitted its first annual progress report to Congress last week, providing an overview of actions the agency has taken and the progress made to date. We look forward to hearing more about that progress today.

Also, pursuant to FDASIA, this morning the Government Accountability Office (GAO) issued a final report on drug shortages. The report contains a thorough assessment of the many factors that could lead to drug shortages. In the report, GAO also examines the role of FDA and makes several recommendations about how the agency could improve on its efforts.

Fortunately, the number of new drug shortages was down in 2012 and again in 2013. While this is certainly a positive sign that things may be moving in the right direction, we know a great deal of work remains. Drug shortages have recently plagued our health care system on many levels, from newborns not receiving their necessary nutrients to cancer patients receiving alternative therapies that may be less effective. Now we are hearing of the impact saline shortages are having in hospitals throughout the country. Our work will continue until all patients receive the medications they need and the peace of mind they deserve.

###