Press Release

GPhA Reveals the Accelerated Recovery Initiative: An Unprecedented Multi-Stakeholder Proposal to Address Drug Shortages

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WASHINGTON, D.C. (DEC. 15, 2011) – The Generic Pharmaceutical Association (GPhA) today reaffirmed its commitment to minimizing current and future shortages of critical drugs with the proposal of a new, unprecedented multi-stakeholder initiative designed to accelerate the recovery of critical drugs in short supply to patients in need.

This proposal, known as the Accelerated Recovery Initiative (ARI), is predicated on voluntary communication between an independent third party and stakeholders involved in the manufacturing and distribution of generic injectable medications currently in shortage. It is designed to use real-time supply and distribution information to give stakeholders — including, but not limited to, manufacturers, wholesalers, distributors, Group Purchasing Organizations (GPO' s) and the FDA — a better understanding of current conditions and expand the supply of critical medications to patients in need.

" The generic industry has taken a leading role in responding to this crisis, and the ARI marks a significant step in those efforts," said Ralph G. Neas, President and CEO of GPhA. " This type of multi-stakeholder collaboration is exactly what is required to respond to this crisis. While this remains a complex issue that cannot be solved overnight, the ARI would significantly enhance our ability to reverse the drug shortages currently afflicting patients and prevent further ones from occurring."

The Accelerated Recovery Initiative calls for:

- An independent third party to gather current and future supply information from stakeholders for products identified as meeting the critical criteria;
- That information to be used to determine current and potential supply gaps, with a focus on those products where a shortage is expected to last longer than 90 days; and

- A high-level SWAT team to be formed within FDA with the ability to quickly respond to critical shortages and work with the current Drug Shortage Staff expanded through the President's drug shortage initiative.

This voluntary initiative will take place in conjunction with the excellent work currently being done by the FDA to expedite regulatory reviews and work closely with manufacturers. It will maintain robust competition, and will not in any way deal with pricing information. It will also require prior acceptance by the Federal Trade Commission and the Department of Health and Human Services. The type of information gathered and disseminated will increase early visibility and communication between the FDA and industry relating to current and potential drug shortages.

" There can be no question that generic manufacturers are in the business of supplying medicine and assuring that consumers and patients have access to the drugs they need," Neas said. " GPhA remains committed to working with all stakeholders to address this crisis. A lack of supply of a critical drug can be devastating, even if it impacts only one patient."

Further details of the initiative can be found in Neas' testimony Thursday before the Senate Committee on Health, Education, Labor and Pensions. A copy of the testimony is available here.

GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 78 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending. Additional information is available at gphaonline.org.