

# CDER Drug Shortage Workshop

Presentation by  
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# Disclosure Statement

- NO CONFLICTS

# Presentation Overview

- The Global Generic Pharmaceutical Industry
- Overview of the Drug Shortage Crisis
- Key Facts About Drug Shortages
- Contributors to Shortages with Proposed Solutions
- Opportunities for Generic Manufacturers
- Summary

# Generic Pharmaceutical Industry

- Pharmaceutical manufacturing is global -- active pharmaceutical ingredients, inactive ingredients and finished doses are sourced, manufactured and distributed by companies around the world.
- Nine of the world's 10 largest drug manufacturers by volume are generic companies.
- Of the 4 billion prescriptions dispensed in the U.S. in 2010, more than 3 billion were filled with generic drugs. (*IMS Health*)
- Generic drugs sold in the U.S. must pass the FDA approval process to show that they are equivalent to the counterpart brands in safety, performance characteristics, intended use and quality. FDA's cGMP regulations apply equally to generic manufacturers and brand drug manufacturers.
- GPhA member companies manufacture 90% of the generic drugs used in the U.S.
- The use of generic prescription drugs saved the U.S. healthcare system \$937 billion over the past decade; \$158 billion in 2010 alone. (*IMS Health*)

# Generic Industry's Principal Position

As members of the public, who also are affected by shortages, the generic industry is devoted to working with all stakeholders to minimize current shortages and mitigate factors that could contribute to future shortages.

Drug shortages are complex and are a multi-stakeholder issue. Our industry is resolute in its commitment to be part of the solution to decrease drug shortages.

# Drug Shortages: An Overview

- The solution to the drug shortage issue transcends the generic industry and involves:
  - brand manufacturers
  - active ingredient suppliers
  - component suppliers
  - wholesalers and distributors
  - Group Purchasing Organizations (GPO's)
  - health care providers
  - FDA, DEA, and other government agencies
- A significant percentage of shortage products are injectables that require specialized manufacturing facilities with finite production capacity.
- The generic industry is acutely aware of the distress caused to patients, families and clinicians by the shortage of medically necessary drugs.

# Facts about Drug Shortages

- ✓ Contrary to some media reports, manufacturers do not deliberately reduce supply of essential medicines to push prices up.
- ✓ Generic manufacturers strongly oppose the actions of opportunistic “grey market” distributors who purchase supplies and then resell them at much higher prices.
- ✓ Drug shortages are typically not caused by a manufacturer’s decision to voluntarily discontinue supplying the product.
- ✓ Any supply shortage from one company could create challenges for other companies to meet additional demands, particularly where special facilities are required, such as in oncology.

# Drug Shortages: Causes and Proposed Solutions

## Cause

- Insufficient early collaboration and communication between industry and the FDA with respect to regulatory actions that could impact supply of critical drugs.

## Proposed Solutions

- Suppliers and the FDA should work together to develop best practices to prevent drug shortages.
  - Need for increased early communication between FDA and regulated industry relating to proposed or contemplated regulatory actions that would effect the supply of critical drugs.
  - Need for process whereby remedial measures could be implemented without completely disrupting the manufacturing of necessary products.
- Enhanced intra-agency dialogue within FDA.

# Drug Shortages: Causes and Proposed Solutions

## Cause

- Manufacturers face a very extensive process to qualify an alternate active pharmaceutical ingredient (API) supplier and/or alternate manufacturing facility. As a result, many drugs have only one API supplier or manufacturing site approved in their applications.

## Proposed Solutions

- New or alternate raw material suppliers and/or alternate manufacturing facilities could be approved through a more streamlined and timely process, thus allowing manufacturers to increase production of medicines in short supply sooner.
- In the event an API supplier ceases production or is otherwise unable to provide adequate supply of raw material, the authority to approve new or alternate suppliers through a CBE-30 supplement would allow a manufacturer to more quickly respond to a shortage situation.

# Drug Shortages: Causes and Proposed Solutions

## Cause

- Inability to source sufficient API for controlled drugs due to the annual manufacturer-specific allocations of these materials established by the Drug Enforcement Agency (DEA). Demand fluctuations and shifting markets change over the course of a year contributing to shortages of controlled drugs. There currently are several controlled drugs on the shortage list.

## Proposed Solution

- The DEA should be required to monitor the use of controlled drugs and adjust allocations accordingly for products in short supply. CDER and the Attorney General should establish a process to streamline manufacturing production quotas in response to drug shortages.

# Drug Shortages: Causes and Proposed Solutions

## Cause

- Lack of formal communication process throughout all stakeholders when reporting and updating drug shortages.

## Proposed Solution

- Implement a formal process and communication flow throughout the supply chain in which manufacturers communicate real and potential shortages.
  - FDA Drug Shortage currently plays an important role as a conduit to communicate the supply status of critical shortage drugs amongst manufacturers and other branches of the FDA.
  - Need to incorporate formal communication process (beyond Drug Shortage and manufactures) to include wholesalers/specialty distributors and GPO's.

# Opportunities for Generic Manufacturers

- ▶ Work with FDA to develop guidance that better outlines the process for suppliers to proactively report drug shortages to the FDA's drug shortage staff.
- ▶ Work with the FDA to develop a defined and updatable list of all medically necessary drugs.
- ▶ Where possible, maximize capacity and redundancies for medically necessary drugs. Generic manufacturers are currently working with FDA to prioritize the supply of medically necessary drugs.
- ▶ In partnership with the FDA, develop successful strategies to assure the highest quality while concurrently aggressively addressing any manufacturing issues.

# Drug Shortages: Summary

- As members of the public, our employees and families similarly are affected by shortages. Industry is committed to working with FDA and other stakeholders to minimize current shortages and prevent future shortages.
- Drug shortage issues are complex and are not limited to the generic drug industry—brand drug manufacturers, active ingredient suppliers, wholesalers, distributors, GPO's, health care providers, and the FDA all have opportunities to be part of the solution to decrease drug shortages.
- While many factors can cause drug shortages, the most serious shortages are often unexpected. Solutions should focus on both the current shortages and minimizing the risk of future shortages.
- FDA and industry should re-examine current policies regarding identifying and addressing potential drug shortage issues.

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