



Cancer  
Research  
Education

# CaRE Presentation

Colorado Cancer Research Program  
[www.co-cancerresearch.org](http://www.co-cancerresearch.org)  
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## Drug Shortages

**October 2011**

**Sponsored by:**

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# Overview

The following information was provided by the  
Federal Drug Administration (FDA) in a  
nationally held webinar on  
September 30<sup>th</sup>, 2011

# The Problem

- In some situations the drug in short supply is curative and no meaningful clinical option exists.
- There is a certainty or strong reason to believe the likelihood of cure or outcome is significantly diminished using an alternative.
- The side effects or quality of life is worse under alternate drugs.
- There may be lack of scientific evidence to know when the alternative drug is equally effective.
- The alternate drug may be more expensive

*Source: W. Charles Penley, MD*

*American Society of Clinical Oncology, September 23, 2011*

# Reasons for Drug Shortages

- Raw Material Shortage
- Manufacturing stoppages due to product quality issues
- Product discontinuations
- Market Shifts – Financial viability for manufacturer
- Change in inventory models
- Types of drugs are not only oncology drugs but all types of drugs.

# Scope of Problem

- In 2005 there were 61 shortages reported to the FDA
- In 2010 there were 178 drug shortages reported to the FDA
- A majority of the shortages are produced by only 7 manufacturers
- Drug shortages affect cancer clinical trials. The NCI is sponsoring 96 clinical trials currently that include 5 drugs that have major shortages (doxorubicin, daunorubicin, 5-FU, paclitaxel, bleomycin and cytarabine).
- Clinical trial participation and enrollment in cancer clinical trials is being impacted.

# Current Relevant Authority

- Reporting of a shortage by a manufacturer to the FDA is voluntary.
- The FDA cannot dictate the production quantity.
- The FDA cannot dictate pricing of drugs

# Once a Shortage is Reported

- When the FDA is notified of a shortage they work with the manufacturer to mitigate the problem
  - Encourage remaining manufacturers to increase production
  - Expedite issues related to shortages (changes in specifications, new raw material sources)
  - In rare cases allow temporary importation from unapproved sources