

# FDA Inspections Find Issues at Compounding Pharmacies

USA  
April 2013

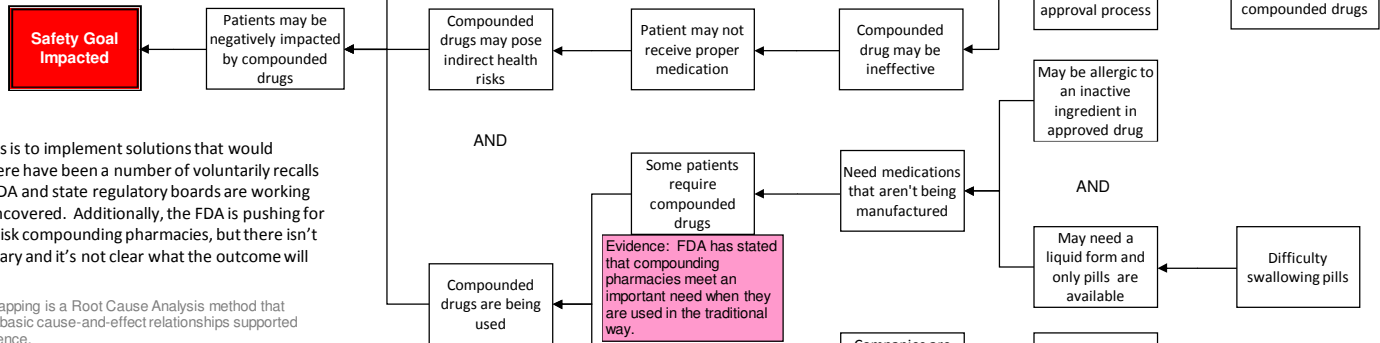
Unsafe practices at compounding pharmacies were found during recent Federal Drug Agency (FDA) inspections. The FDA visited about 30 pharmacies in 18 different states, focusing on the production of sterile drugs which was determined to be the highest risk to patient safety. The inspection findings include a number of potential contamination issues such as inadequate ventilation, unidentified particles in vials of supposedly sterile medications, cleanliness issues in clean rooms such as rust and mold, and insufficient microbiological testing. Interest in compounding pharmacies was increased after the fall 2012 outbreak of fungal meningitis that killed 50 and sickened hundreds was traced back to compounded injectable steroid medication that had been shipped across the country.

## 1 Problem

<b>What</b>	Problem(s)	Contaminated compounded drugs making patients ill, contamination issues at compounding pharmacies
<b>When</b>	Date	FDA inspection findings released April 2013
	Differences	Use of compounded drugs
<b>Where</b>	Physical Location	USA
	Task being performed	Compounding drugs, especially injectable medications
<b>Impact to the Goals</b>		
	<b>Safety</b>	Patients may be negatively impacted by compounded drugs

This incident ??

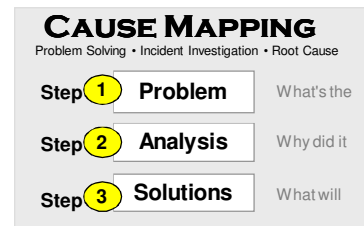
## 2 Analysis



## 3 Solutions

The final step in the Cause Mapping process is to implement solutions that would prevent the problem from reoccurring. There have been a number of voluntarily recalls as a result of the recent inspections. The FDA and state regulatory boards are working together to address the issues that were uncovered. Additionally, the FDA is pushing for new legislative authority over the highest-risk compounding pharmacies, but there isn't agreement on whether changes are necessary and it's not clear what the outcome will be.

Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.



**Cause Map**

High Level

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