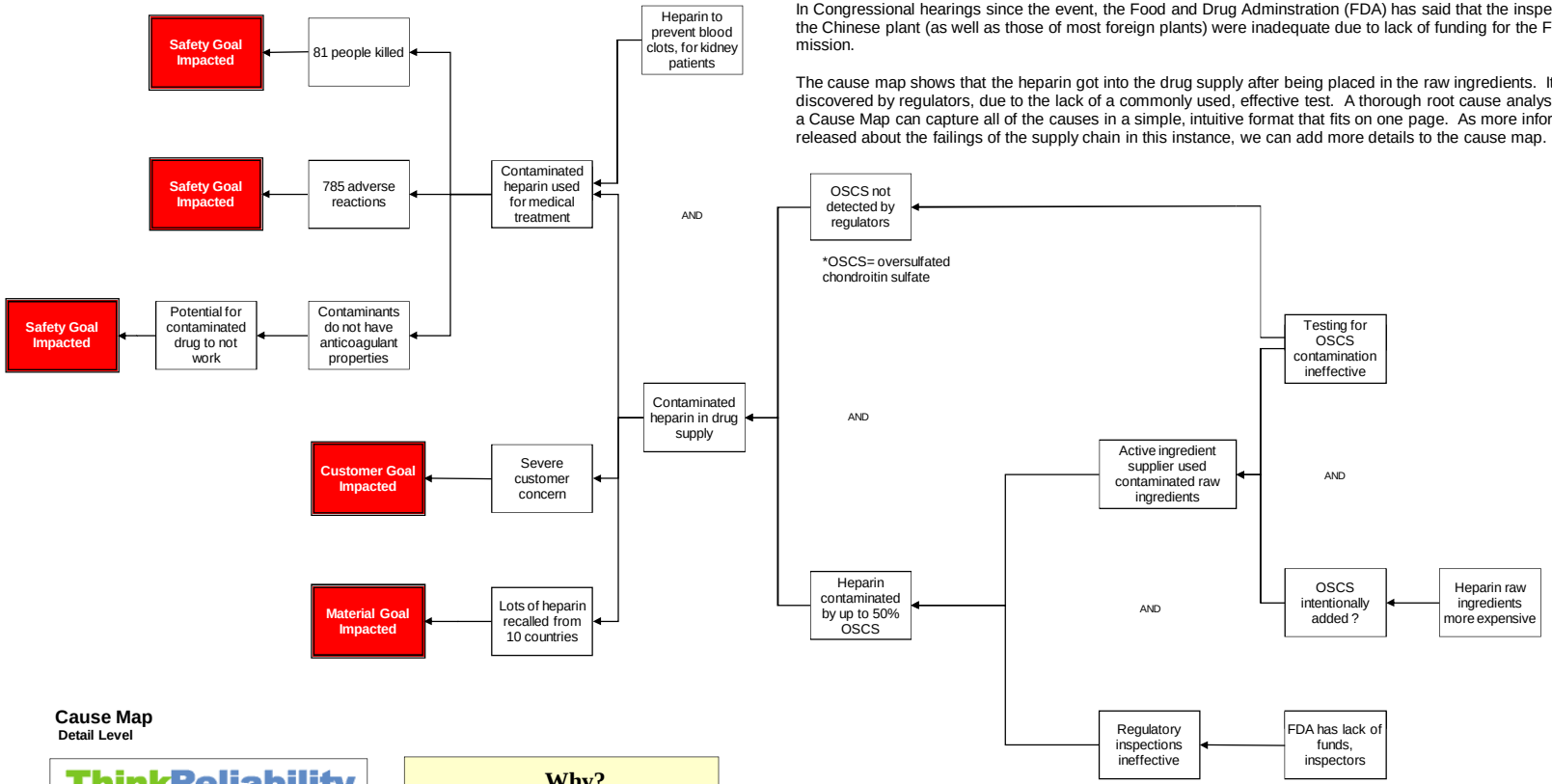
Heparin Contamination

In early 2008, contamination of the U.S. supply of heparin was brought to light. A significant portion of the U.S. supply of heparin was recalled, and the death toll potentially associated with the contamination has now climbed to 81, with hundreds of adverse events also reported. Additionally, prior to the recall there was concern for deaths and injuries associated with the contaminated drug not fulfilling its expected purpose - preventing blood clots during surgeries and kidney dialysis - because the contaminant has no blood thinning properties. The contaminated drug has been found in at least 10 countries, increasing concern about the drug supply chain.

Researchers have verified that the contaminant in the recalled heparin is oversulfated chondroitin sulfate (OSCS) and that they have discovered a mechanism by which the contaminant can cause the adverse effects (falling blood pressure and severe allergic reactions). Additionally, the researchers have provided a test for regulators to screen heparin for this contaminant.

They have determined that the OSCS was present at the active ingredient supplier plant in China. Because OSCS does not occur in nature and mimics the chemical structure of heparin so closely, it is believed that the (mostly unregulated) crude heparin suppliers in China added OSCS to increase their profit, as OSCS is many times less expensive than heparin. The OSCS was not detected by standard impurity tests, due to its similarity with heparin. In Congressional hearings since the event, the Food and Drug Adminstration (FDA) has said that the inspections of the Chinese plant (as well as those of most foreign plants) were inadequate due to lack of funding for the FDA mission.

The cause map shows that the heparin got into the drug supply after being placed in the raw ingredients. It was not discovered by regulators, due to the lack of a commonly used, effective test. A thorough root cause analysis built as a Cause Map can capture all of the causes in a simple, intuitive format that fits on one page. As more information is released about the failings of the supply chain in this instance, we can add more details to the cause map.



Cause Map
Detail Level

ThinkReliability
Houston Office 281-489-2904
www.ThinkReliability.com

Why?

Effect ← Cause

NOTE: Read the Cause Map from left to right with the phrase "Was Caused By" in place of each arrow.