

FDA Recommends Lower Doses of Sleep Aids

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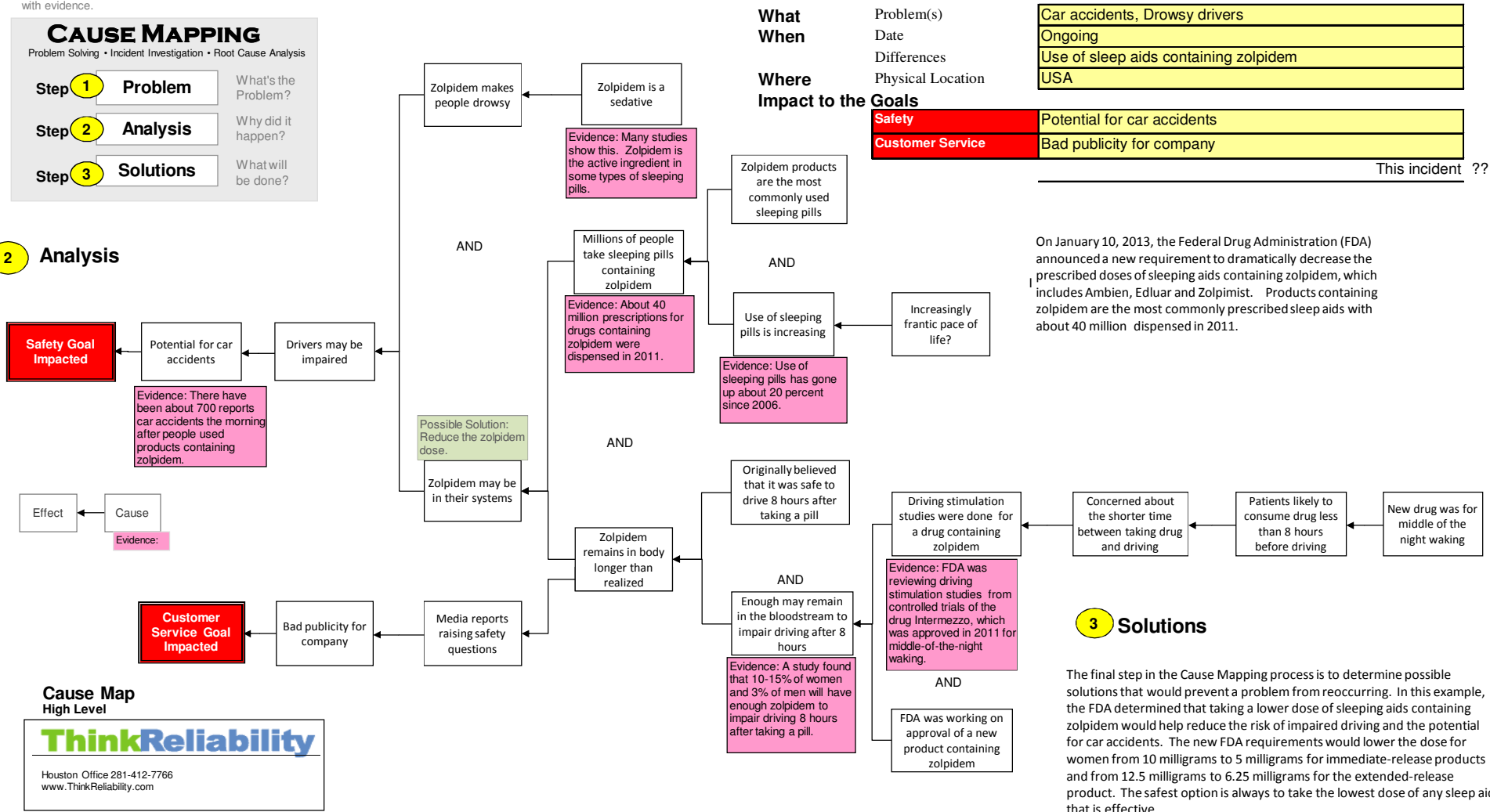
Cause Mapping is a Root Cause Analysis method that captures basic cause-and-effect relationships supported with evidence.

CAUSE MAPPING

Problem Solving • Incident Investigation • Root Cause Analysis

- Step 1 **Problem** What's the Problem?
- Step 2 **Analysis** Why did it happen?
- Step 3 **Solutions** What will be done?

2 Analysis



1 Problem

Problem(s)	Car accidents, Drowsy drivers
Date	Ongoing
Differences	Use of sleep aids containing zolpidem
Physical Location	USA

Safety	Potential for car accidents
Customer Service	Bad publicity for company

This incident ??

On January 10, 2013, the Federal Drug Administration (FDA) announced a new requirement to dramatically decrease the prescribed doses of sleeping aids containing zolpidem, which includes Ambien, Edluar and Zolpimist. Products containing zolpidem are the most commonly prescribed sleep aids with about 40 million dispensed in 2011.

3 Solutions

The final step in the Cause Mapping process is to determine possible solutions that would prevent a problem from reoccurring. In this example, the FDA determined that taking a lower dose of sleeping aids containing zolpidem would help reduce the risk of impaired driving and the potential for car accidents. The new FDA requirements would lower the dose for women from 10 milligrams to 5 milligrams for immediate-release products and from 12.5 milligrams to 6.25 milligrams for the extended-release product. The safest option is always to take the lowest dose of any sleep aid that is effective.

Cause Map
High Level



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