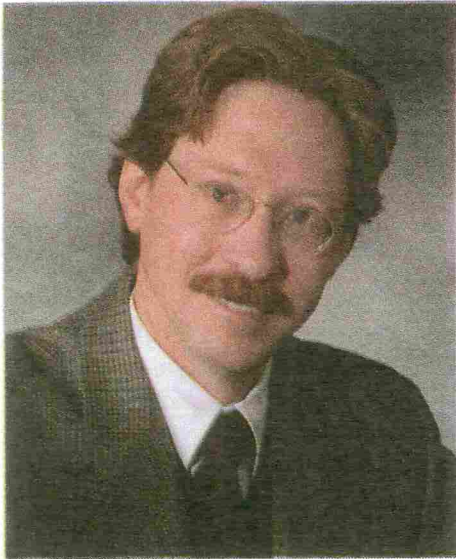


## The ABCs of Product Recalls



by R. Michael Shickich

The Food and Drug Administration (FDA) is the agency charged with ensuring the safety of our drugs, medical devices, cosmetics, and most of our food. If it discovers that some regulated product is dangerous, the FDA may order a recall, a multistep process.

First, a problem must come to the FDA's attention, which can happen in a number of ways. Often, the company that made the product will submit a report that prompts a

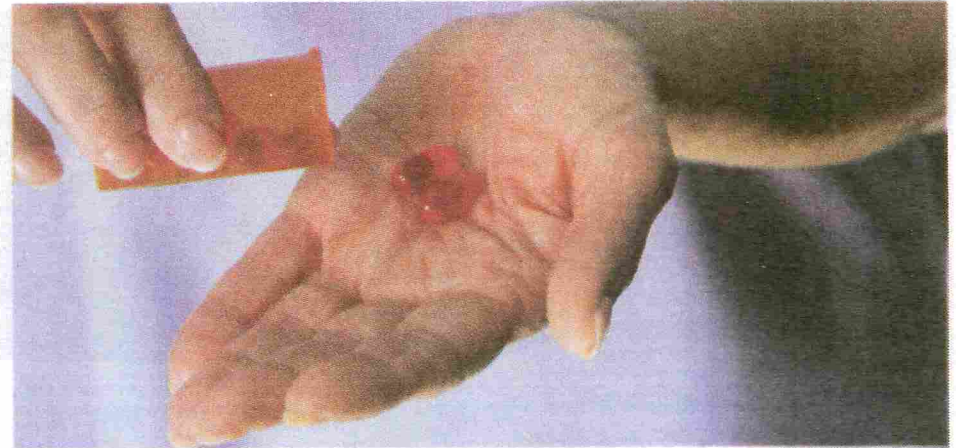
recall. At other times, the FDA's inspectors will discover a problem, such as during an inspection of a factory. Or it can happen that other government agencies, like the Centers for Disease Control, will tell the FDA of possible issues.

Finally, many recalls are prompted by reports made by consumers: If consumer reports show a pattern of problems with a product, the product may be recalled.

FDA recalls fall into one of three categories, depending on the level of danger a product poses. Class III recalls are for problems unlikely to be dangerous, such as when a label is done improperly. Class II recalls are more serious, involving products that present a danger, albeit one that is not life-threatening.

Class I recalls are very serious and are issued when a product presents a danger of serious health problems or death. In order to spread the word as quickly as possible, the FDA widely advertises Class I recalls in the media. Although usually only Class I recalls trigger FDA media alerts, information regarding all levels of recall can be found on the FDA's website.

After a recall has been issued, the FDA will often follow up to see if the recall has



been effective. It may check to ensure that the product has been removed from shelves or that the problem has been fixed. It also makes sure that the defective product has been destroyed.

If you have access to the Internet, you can check on recent product recalls at the FDA website at [www.fda.gov](http://www.fda.gov). Recalls are categorized into groups such as food, drugs, medical devices, animal & veterinary, cosmetics, etc.

Whether caused by a mistake or by disregard of the law, defective products are dangerous. FDA recalls protect the public from these dangers.

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*R. Michael Shickich is the founder of the Injury Law Firm located in Casper. The focus of his practice is personal injury and wrongful death cases.*