FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Medical Device Recalls: An Overview

CDRH Perspective
Erin Keith, Associate Director
Compliance and Quality Staff, OPEQ

Outline

- Definition
- Purpose
- Activities
- Process

Defining Recalls

- Effective method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA).
  - Correction: remediating actions take place at the device location
  - Removal: the device location is moved to perform the remediation actions

Defining Recalls

- Voluntary actions by manufacturers
- Protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective
- Most often self identified by manufacturers
- Can be requested or mandated by the FDA in urgent situations

Purpose of a Recall

1

Contain and ***control*** the risks to health from the violative device

2

Correct the issue in the field or ***Remove*** the device from use

3

Prevent the issue from recurrence.

Recall Activities

Manufacturer

- Responsible for recalled device
- Develop and implement recall strategy
- Notify customers of recall issue and instructions
- Report recall information to the FDA

The FDA

- Request recall when appropriate
- Assess risk and classify recall
- Oversight of recall strategy and effectiveness
- Intervene when risk is not adequately mitigated

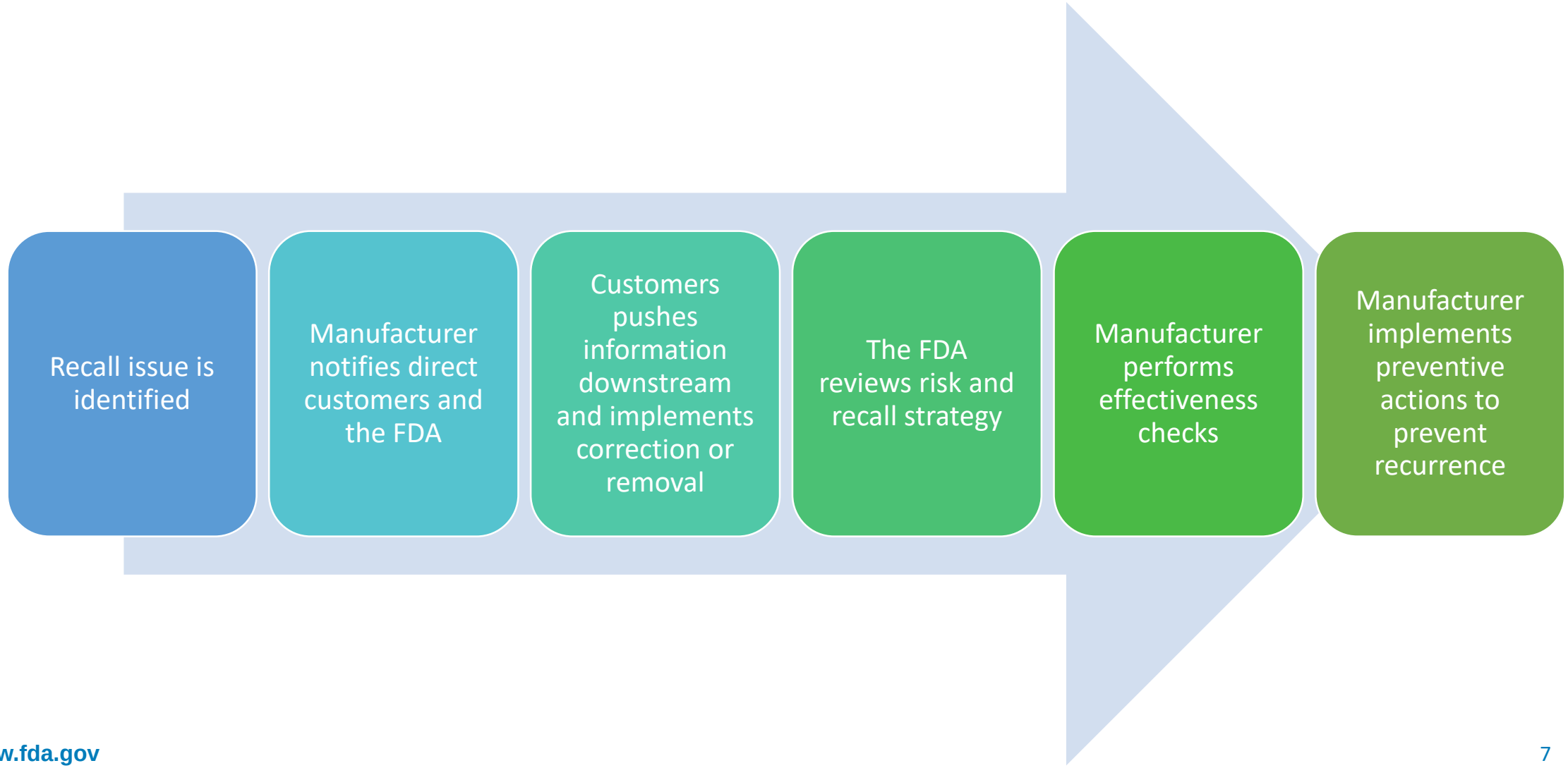
Health Care Providers

- End users of the device
- Evaluate benefits and risks of implementing a recall
- Communicate with patients

Patients

- End users of the device
- Evaluate benefits and risks of implementing a recall

Recall Process



Recall Initiation

Common causes for medical device recalls include:

- General medical device or specific component failure
- Design flaws
- Inadequate instructions for use
- Package integrity problems for medical devices marketed as sterile
- Not obtaining the required FDA authorizations, prior to marketing the product

A healthy quality management system is designed to recognize these issues

FDA Review Impacting Communication

Scope

The extent of the affected devices included in the recall.

Recall Classification

Indication of the relative degree of risk to health presented by a recalled product.

Recall Strategy

A comprehensive plan of action to be taken in conducting a specific recall.

Benefits of UDI for Recalls

FDA's Unique Device Identification (UDI) system involves placing a human- and machine-readable code on most medical devices, so that the FDA, manufacturers, health care providers, patients and others can more easily identify medical devices.

This system may also facilitate rapid identification of medical devices affected by a recall and help health care providers and patients get the information they need.

Summary

Recalls are an effective way of addressing unexpected issues that emerge with products on the market

The FDA, medical device industry, and others share responsibility for informing patients and the public about medical device recalls

The FDA is engaging stakeholders to identify opportunities to do so more clearly and effectively, in a timely fashion, and in ways that are relevant and of most benefit to patients


FDA
U.S. FOOD & DRUG
ADMINISTRATION