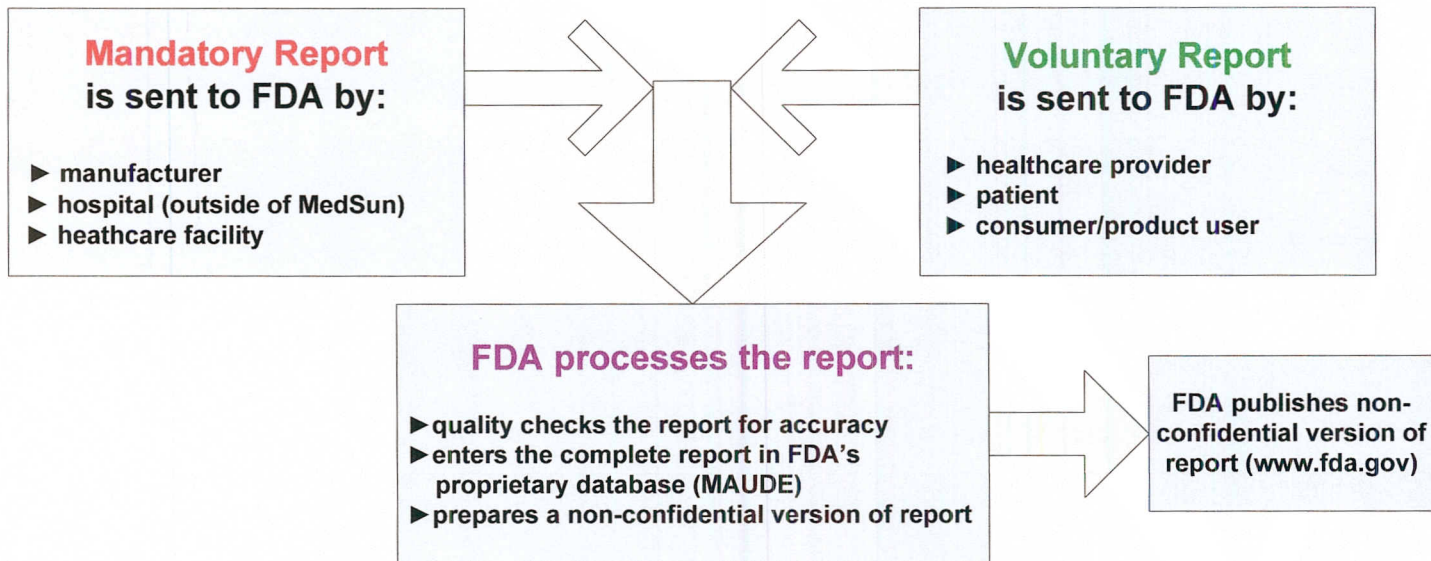


What Happens to an Adverse Event Report submitted to FDA?



FDA reviews and analyzes the adverse event report, which results in (one or more of) these actions:

- ▶ focused monitoring of adverse events by FDA for trends
- ▶ request from FDA to submitter of report for additional details about the adverse event
- ▶ device recall by device manufacturer
- ▶ change in device design by device manufacturer
- ▶ change in device labeling (e.g., changes in instructions) by device manufacturer
- ▶ decision by device manufacturer to stop selling device
- ▶ issuance of Public Health Notification (PHN) by FDA to healthcare providers; PHNs usually describe a risk associated with device use and provide recommendations on reducing risk
- ▶ issuance of safety-related communication by FDA intended for patients or consumers
- ▶ FDA inspection of device manufacturer
- ▶ testing of device by FDA scientists
- ▶ change in FDA's future regulatory decisions (test methods/ requirements, design, labeling)