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F.D.A. Steps Up Oversight of Infusion Pumps

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The New York Times reports the Food and Drug Administration plans to "tighten their oversight" of medical devices, including infusion pumps that automatically deliver drugs and food to hospital patients. Last week the FDA issued guidelines requiring manufacturers of the pumps to provide the agency with more test data than previously required for approval. One reason for this action is that the FDA has received reports over the past five years of 710 patient deaths, and some officials suspect the actual number may be far higher. In those five years there have been 79 recalls of infusion pumps — the highest number of recalls for any medical device.

The biggest makers of infusion pumps include Baxter Healthcare of Deerfield, Ill.; Hospira of Lake Forest, Ill.; and CareFusion of San Diego. Here are excerpts from the article:

Infusion pumps normally use software to automatically control both the rate and volume of a medication's flow. To set a pump for an individual patient's needs, a doctor, a nurse or other health care worker enters information by using the buttons on a pump's keypad, which resembles that of a phone.

Pump manufacturers say that most problems occur when a nurse or health care worker enters the wrong data accidentally. F.D.A. officials said, however, that based on their

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review of pump complaints they thought many deaths and injuries related to the devices were less the result of user error than of product design and engineering.

For example, agency officials said that some pumps were prone to key bounce, a problem in which defective software interprets a single keystroke as two separate presses of that key. For example, instead of dispensing two units of a drug, a pump would dispense 22 units.