

21 U.S. Code § 360h-1

Program to improve the device recall system

(a) In general

The Secretary shall—

- (1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;
- (2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

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