PATIENT SAFETY BLOG

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Unsafe Medical Devices: The Problem Isn't "Over-Regulation"

August 4, 2011 by Patrick A. Malone

The latest report from the prestigious Institute of Medicine -- about the nonsensicality of the current system where dangerous medical devices can get approved for sale with a grandfathering process called 510-k -- prompted this letter to the editor that summed it all up:

The problems are not new. They reflect an underfinanced and underpowered Food and Drug Administration, successful efforts by the device industry to block or blunt regulation, and the industry's relationships with corruptible surgeons and members of Congress.

In the current ideological climate, we will hear a great deal about the dangers of "overregulation." One must hope that the F.D.A. will be allowed to pay more attention to the Institute of Medicine than the onslaught from industry lawyers and lobbyists.

The author is HENRY GREENSPAN, who teachers ethics, politics and regulation at the University of Michigan, writing in the New York Times.

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