TRADING SAFETY FOR INNOVATION AND ACCESS: AN EMPIRICAL EVALUATION OF THE FDA'S PREMARKET APPROVAL PROCESS

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Congress created the Premarket Approval (PMA) process to provide a rigorous safety evaluation of high-risk medical devices before they may be sold on the U.S. market. Evaluating a PMA application requires the FDA to conduct a lengthy, complex, and costly assessment of the extensive data a manufacturer must submit. But other policy concerns, notably a fear of hampering innovation and a desire to assure timely access to new technologies, have led Congress to relax some of the rigorous data requirements the PMA process imposes on manufacturers. Congress mandates that the FDA employ the "least burdensome" approach to regulation that allows a reasonable assurance of safety. The FDA has interpreted this as permitting it, among other things, to approve high-risk devices based on small, short-duration clinical trials the designs of which fall short of the most rigorous scientific standards. Congress also created "PMA Supplement" pathways that allow manufacturers to modify their PMA-approved devices with only limited supporting data. And Congress included several provisions in the recently-enacted 21st Century Cures Act that further tip the balance away from ensuring device safety.

Scholars writing in the medical literature have raised concerns that the standards for PMA approval have become too relaxed, potentially compromising device safety. But most empirical studies have focused on the less rigorous 510(k) pathway, which is designed for low- and medium-risk devices. These studies provide limited evidence about how frequently PMA-approved devices fail. And no empirical work has examined whether these failures are related to the statutes and regulations through which Congress and the FDA have attempted to balance safety against innovation and access. This Article begins such an examination, presenting the results of a new empirical study of PMA-approved devices. The study finds that at least 4.6-6% of PMA-approved devices will fail in such a way as to threaten death or serious and permanent

harm. Complex cardiovascular devices and devices that have been frequently and rapidly modified through certain PMA supplements are most likely to fail.

Based on the concerns that have been raised and on the findings of this study, this Article suggests that Congress and the FDA should take steps to readjust the balance between safety on one hand and innovation and access on the other. The FDA should insist on scientifically rigorous, longer-duration clinical trials before approving PMA applications. Further, the FDA should limit the number of significant modifications that manufacturers of certain devices are permitted to make to a device through PMA supplements before a thorough safety assessment is required, and should limit how soon after one significant modification is approved that a second modification will be considered. Finally, Congress should amend the 21st Century Cures Act to avoid further tipping the balance between safety, innovation, and access away from the FDA's primary mission of ensuring medical device safety.