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RESEARCH SUMMARY

EFFECTS OF THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT ON FDA REVIEW TIMES FOR MEDICAL DEVICES

In the United States, many life-saving medical devices must undergo review and approval by the Food and Drug Administration (FDA) before they can enter the market. In an effort to streamline this process, Congress passed the Medical Device User Fee and Modernization Act (MDUFA), which levied user fees on device manufacturers in exchange for the promise of faster review times.

Using data provided by the FDA, a new study for the Mercatus Center at George Mason University examines whether the MDUFA was successful at shortening the review process. The results suggest that the MDUFA did not have a significant effect on review times, and followed a decade in which review times were improving before MDUFA was enacted. Other policy changes are required in order to ensure that patients have timely access to life-saving therapies.

To read the study in its entirety and learn more about its authors, Eric Sun, an economist, doctor, and instructor at the Stanford University School of Medicine, and Kelly M. Ferguson, a Mercatus MA fellow, see "Effects of the Medical Device User Fee and Modernization Act on FDA Review Times for Medical Devices."

BACKGROUND AND STUDY DESIGN

In 2002 Congress passed the MDUFA, requiring the FDA to "assess and collect fees from manufacturers for review of medical device applications, with the intent of expediting review of device applications." Under the MDUFA, medical device manufacturers have to pay steep user fees to the FDA when seeking approval for devices, in exchange for the promise that the FDA will make its decisions more quickly.

Benefits of Shortening Approval Times

Shortening medical device approval times could save lives—one study found that 47 percent of drug-eluting stents used to treat myocardial infarction (heart attacks) that were available in the European Union were not available in the United States at the same point in time. Other studies

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have found that drug approval times are generally longer in the United States than in European countries, although one study found the opposite.

Medical device companies pay hundreds of thousands of dollars in fees to the FDA in the understanding that the FDA has the resources to put medical devices through the mandatory approval process quickly. This understanding and the implications review times have for patient health make it important to determine whether the MDUFA has actually shortened review times. An empirical regression analysis of data the FDA has provided on review times can answer this question.

Scope of Previous Literature

Previous literature has focused on devices approved under the premarket approval (PMA) process, which is reserved for devices posing the highest risk to human health and involves substantial premarket clinical testing akin to the testing required for pharmaceuticals.

More Comprehensive Study of Medical Devices

This study examines devices approved under the PMA process, but also expands the analysis to include devices approved under a less stringent process, the 510(k) process, which accounts for the vast majority of devices requiring premarket approval. During the time period studied, there were 825 devices seeking approval through the PMA process and 67,491 devices seeking approval through the 510(k) process, indicating that inclusion of the 510(k) devices will produce better empirical results.

KEY FINDING: THE MDUFA FAILED TO REDUCE REVIEW TIMES

The MDUFA (both the 2007 law and its 2012 reauthorization) was associated with a small statistical increase in approval times, the exact opposite of the policy's intended effect:

- *Before the MDUFA there was a decline in approval times.* During the pre-MDUFA era (1991–2002), review times for medical devices seeking approval fell by 8 percent annually for PMA applications and by 4.5 percent annually for 510(k) applications.
- *After the MDUFA the annual decline in approval times got smaller.* This trend continued unabated during the MDUFA era (2003–2008) as well as the period covered by the law's subsequent reauthorization (2008–2012), with the data showing a very small annual decline in device review times. The MDUFA has not achieved its intended goals for either the PMA process or the 510(k) process.

CONCLUSION

The MDUFA comes up for reauthorization every five years as part of a larger FDA authorization law. Heading into the 2017 reauthorization, the findings in this study should give pause to any policymaker seeking to continue the current, failed status quo. Policymakers should consider different approaches to give the FDA the revenue it purports to need in order to approve medical devices in a timely fashion.