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RESEARCH SUMMARY

US MEDICAL DEVICES
Choices and Consequences

Approval of new medical devices by the Food and Drug Administration (FDA) costs an exorbitant amount of money relative to development costs, and the path to bring a product to market is long, complex, and uncertain. Any significant improvement to a device, something that is part of the normal path of innovation, requires approval by the FDA, which discourages innovation. The FDA's laws and practices are outdated and unable to keep pace with what could be rapid technological change and growth leading to better patient outcomes.

A new paper for the Mercatus Center at George Mason University shows why the current system of medical device approval discourages technological innovation and ultimately affects patient choice. The approval process could be improved by introducing competition for approval—a process that already exists in the European Union. Private evaluation organizations, which already evaluate products and make approval recommendations, and the FDA can compete to inform patients and doctors about the safety and effectiveness of medical devices. Because each relationship between a doctor and a patient has different risk preferences, all would likely be better served by a system in which the FDA must compete not just on safety and efficacy information, but also on timeliness and cost. Instead of trying to elicit and aggregate patient preferences for a one-size-fits-all decision, product evaluation can serve individual preferences of patients and physicians. This shift in approval structure is appropriate in an era when, unlike the past, negative information that emerges through analysis and use will quickly spread throughout the medical marketplace to both patients and doctors.

To read the paper in its entirety and to learn more about its authors, scholars Richard Williams, Robert Graboyes, and Adam Thierer, see "US Medical Devices: Choices and Consequences."

THE CURRENT SYSTEM OF FDA REGULATION

The Medical Device Amendments of 1976 gives the FDA maximum discretion to ensure the safety and effectiveness of medical devices, with no deadlines for approval. Subsequent laws gave the

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FDA even more control over medical devices and created different approval processes for different types of medical devices. The current system requires significant information and the selection of an approval pathway depending on the product:

- *Approval categories*. Currently, five categories of medical devices are recognized, with the majority of devices falling under the "premarket notification system" known as 510(k). These are products for which there is a device already on the market that is similar to the proposed device. Other approval pathways take even longer, particularly if the device is truly revolutionary.

- *Information disclosure*. The FDA demands an enormous production of information from the inventor of the product, which may be considerably more than what is needed by patients or doctors.

PROBLEMS WITH THE FDA'S CURRENT APPROVAL SYSTEM

There are several identifiable problems with the current approval system the FDA uses:

- *High costs*. Approval can cost tens of millions of dollars to produce what often amounts to thousands of pages of documentation and information for the FDA.

- *Uncertainty*. Inventors and manufacturers looking to market a device lack certainty about the likelihood of a device's approval, and they do not know how much testing the FDA will require before an approval. There is also no certainty about the cost of producing information required by the FDA.

- *Delays*. Approval of a device can take months or years, even after inventors and manufacturers spend years conducting clinical trials. The problems mentioned above create disincentives for inventors to create new products. Delays for those products that do manage to get through can be excessive, potentially causing patients to needlessly suffer or die. In addition, because approval is somewhat easier for a device approved under the 510(k) process, manufacturers have an incentive to make modest, rather than revolutionary, changes in device design. But even for those devices, the FDA requires the same process for every improvement inventors would like to make. Furthermore, the FDA has the incentive to slow down the process for approval because of asymmetric incentives: if it releases a device that harms people, the agency faces harsh criticism; if it harms people by failing to release a device, no ramifications ensue.

- *Technology and society*. The FDA is unable to keep pace with the technological growth and change available in the information technology age. With new advancements in medicine and health occurring at an exponential rate, the FDA's 40-year-old enabling law does not allow the agency to keep up. Although currently a leader in the medical device market, the US risks losing its competitive position without significant changes.

PROPOSED SOLUTION

These problems demand a solution that reforms device approval based on a market process where patients and doctors can assess risks and benefits, rather than relying solely on the FDA. Instead of granting more resources and power to the FDA, Congress should adopt a new model for medical devices.

Combining the best of the current European medical device approval system and an older system for maritime safety (as well as for medical devices), the proposed model would allow private approval bodies to compete with the FDA for the trust of consumers. This system would also allow the FDA to shift some of its resources to become more of an information and enforcement agency.

A new system would include the following:

- *Competition for trust*. Private approval bodies would compete with the FDA for the trust of hospitals, physicians, and patients. Manufacturers of devices could submit their devices to private bodies, which could grant approval based on the safety and effectiveness of the devices. Some firms would specialize in evaluating particular kinds of devices. In turn, patients and doctors would drive choices between private approvers and the FDA. This would create a lively marketplace that would better balance the risks of approving devices more quickly versus the risks of restricting new devices.

- *The FDA's new role*. The FDA could also continue to serve a useful role in setting broad good manufacturing practices standards that could be monitored by nongovernmental bodies for compliance. It could also retain approval for the most risky devices, gather and publish information on post-market issues, and focus on enforcement.

- *Information for patients and doctors*. The information revolution has empowered patients and consumers with greater access to information about medical devices—even more than they can understand. As new devices are developed in the market, offering consumers greater choice, more information will also benefit consumers as they are better able to make decisions impacting their own health and well-being.

CONCLUSION

The FDA is slowing medical device innovation through a cumbersome, expensive, and uncertain approval process. Rather than granting the FDA more authority and more approval options, Congress should create competition in the approval market by allowing competition for approvals. This will create a market in which different patient and doctor preferences regarding risks and benefits can be better served, ultimately improving patient health outcomes.