



FDA-CMS PARALLEL REVIEW A Failed Attempt at Spurring Innovation

In the United States today, it takes an average of \$94 million and 54 months—about four-and-a-half years—for certain new medical devices to clear regulatory hurdles and become available for patients. The Food and Drug Administration (FDA) must approve medical devices, and the Centers for Medicare and Medicaid Services (CMS) must clear those devices for Medicare reimbursement. In Europe, the process takes just 11 months.

In an effort to shorten the approval process and incentivize more medical device innovation, the FDA and CMS devised a “parallel review program” in 2010. A new study for the Mercatus Center at George Mason University finds that the program, while well intentioned, has fallen far short of its intended goals and failed to address the real obstacles manufacturers face in getting medical devices to patients.

To read the study in its entirety and learn more about its author, Marta Podemska-Mikluch, see [“FDA-CMS Parallel Review: A Failed Attempt at Spurring Innovation.”](#)

METHODOLOGY AND DATA

The study outlines the approval processes of both the FDA and CMS to show which medical devices qualify for the parallel review program.

- *FDA’s Process.* The FDA uses a premarket approval (PMA) process to determine whether a device is “safe and effective” for its intended use. PMAs are required for one classification of medical devices—class III devices, which are considered the highest risk (examples include implantable pacemakers and breast implants). FDA-CMS parallel review focuses on new technologies that would be categorized as class III devices.
- *CMS’s Process.* The other qualifying process for parallel review is the national coverage determination (NCD) process conducted by CMS, in which CMS determines whether a medical device is “reasonable and necessary” enough to obtain Medicare reimbursement. Medicare reimbursement can also be approved by local coverage determinations (LCDs), which are conducted by regional Medicare administrative contractors rather than by CMS. NCDs and LCDs are sets of instructions that describe conditions required for Medicare

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coverage and set the stage for reimbursement, which is crucial to manufacturers' revenue streams and profitability.

Additionally, the study examines the number of medical devices approved under the parallel review process as compared to the conventional method to gauge the effectiveness of the pilot program.

KEY FINDINGS AND ANALYSIS

The parallel review process has limited impact. After five years, only two devices are known to have gone through parallel review, and only one device has been approved—a DNA screening test for colorectal cancer. By comparison, in 2015 the FDA issued 43 premarket approvals to devices that did not undergo parallel review.

The parallel review process fails to encourage participation. The parallel review process's eligibility parameters are extremely narrow.

- Only 10 percent of all medical devices are classified as Class III devices subject to the FDA's rigorous premarket approval process and thus eligible for parallel review.
- Also, manufacturers do not need to obtain an NCD to qualify for Medicare coverage. LCDs can also secure Medicare coverage and reimbursement. LCDs are performed regionally and are developed by the Medicare administrative contractors rather than by the CMS. The regional jurisdiction means LCD Medicare coverage guidelines apply only at the local level, allowing manufacturers to avoid the risk of adverse coverage determination at the national level.

The review process may be parallel, but the answers sought by the FDA and CMS approval processes are not. The FDA decides whether a device is "safe and effective" for its intended use, while CMS determines if an item or service is "reasonable and necessary" enough for an NCD and subsequently Medicare coverage and reimbursement.

- A 2013 study suggested that CMS standards are generally more restrictive than those of the FDA, which can mean that producers of medical innovations spend more time and resources trying to obtain an NCD than a PMA.
- Since Medicare coverage can also be determined by LCDs, it is understandable that manufacturers would not wish to be tied to the CMS approval process inherent in a parallel review.

The parallel review process does nothing to address obstacles already facing manufacturers. It does not encompass all regulatory procedures that must be completed, nor does it address flaws within the existing FDA and CMS approval procedures.

- In addition to FDA approval and Medicare reimbursements, medical device manufacturers need to get their products into the Healthcare Common Procedure Coding System. This system requires manufacturers to prove that their new devices are sufficiently different from existing technology and used by enough providers. Parallel review does not include the process of getting a new code.
- The parallel review program does not address unpredictability within the FDA approval process, which already costs manufacturers around \$94 million per device. A recent survey found that disruptions and delays in the premarket approval process, such as key personnel

changes and agency representatives absent from key meetings with companies, were common. Forty-four percent of survey respondents reported personnel changes partway through the PMA process, and 34 percent reported meeting absences.

CONCLUSION

Combining the efforts of two government agencies seems like a logical way to speed up a time-consuming regulatory process. But based on very little demonstrated interest in the FDA-CMS parallel review program, doing so for new medical devices has not worked. Despite this lack of interest, however, regulators have expanded the program to private payers to enable reimbursement from private insurers as well as from Medicare.

Instead of creating a process within the confines of existing regulatory structures at the FDA and CMS, policymakers should focus on real reform within the agencies themselves to provide much-needed relief for manufacturers who develop innovative medical devices and for the patients who use them.