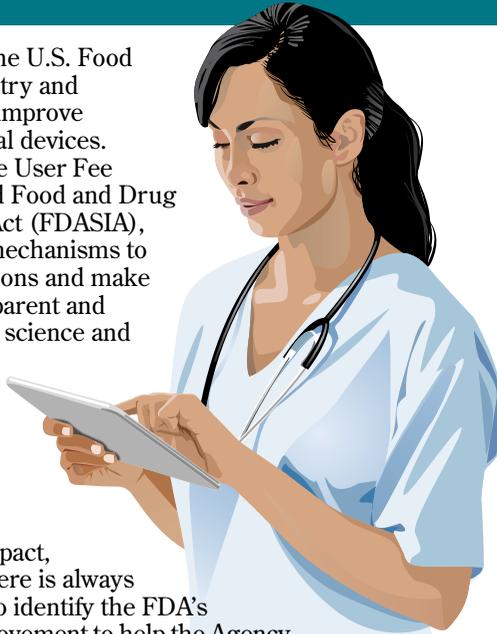


Recent Trends in FDA Medical Device Regulation

Following years of strained relations, the U.S. Food and Drug Administration (FDA), industry and Congress have collaborated closely to improve regulatory review processes for medical devices. Legislation, such as the Medical Device User Fee Amendments of 2012 (MDUFA III) and Food and Drug Administration Safety and Innovation Act (FDASIA), codified industry user fees and other mechanisms to improve industry-Agency communications and make review processes more efficient, transparent and predictable while maintaining rigorous science and safety standards. Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health (CDRH) has also led efforts to better engage with industry and other stakeholders, including patient groups.



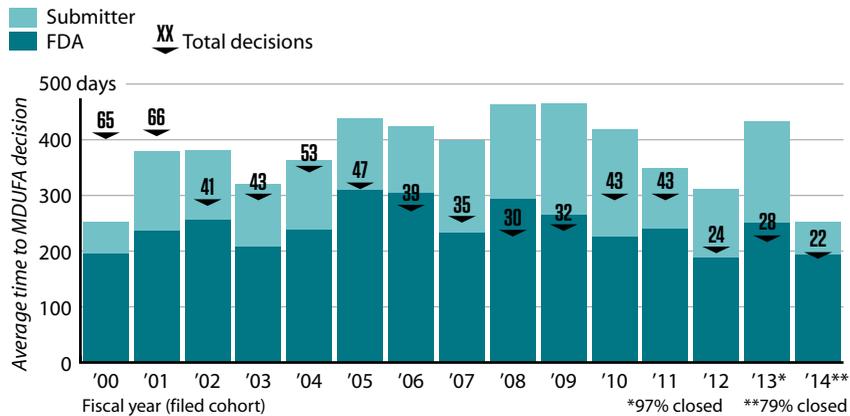
These efforts have had a significant impact, generating tangible gains. However, there is always room for progress. This report seeks to identify the FDA's successes and continued areas for improvement to help the Agency and Congress continue their efforts to refine device review processes.

PMA Trends

Premarket approval (PMA) products comprise complex, higher risk products, such as heart valves, neuromodulation devices and other implantables. After a decade-long trend upwards, PMA review times have improved markedly over the past few years, with the considerable exception of 2013.

PMA ORIGINAL REVIEW TIMES

Average times to MDUFA decisions and total decisions, fiscal years 2000-2014



One factor that may have contributed to the slowdown in 2013 was an increase in the percentage of devices referred for panel review — jumping from 8 percent in 2012 to 36 percent in 2013, a near record.

Panel reviews are often used for innovative, first-in-class products, and the 2013 numbers may reflect a blip rather than a nascent trend. However, the panel-related data may reveal a topic worthy of further study by the Agency and Congress given the implications, especially for small companies, which are particularly sensitive to lengthier review times and the costs or delays in revenue associated with them.

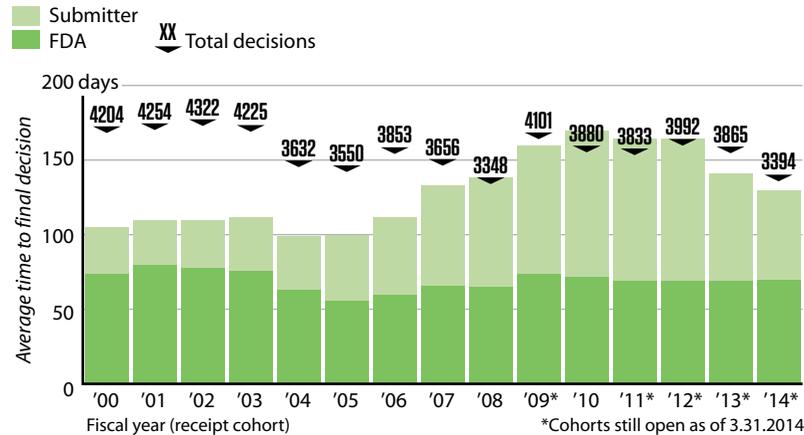
Other data points to an improving environment for PMA product reviews, including an increase in the proportion of products receiving approval or approvable decisions and a reduction and stabilization in the Agency's decision backlog.

510(k) Trends

The latest data show the first signs of improvement for 510(k) products, the bulk of devices reviewed by the FDA. After plateauing at the turn of the decade, clearance times, though still far above historic averages, have shown recent decreases suggesting that they may be turning the corner. Similar to PMAs, the 510(k) backlog has decreased, particularly for submissions pending for more than 90 days.

510(k) DECISIONS

Decisions and average times to final decisions, fiscal years 2000-2014



Conclusion

CDRH has a challenging job: balancing rigorous safety standards with timely, predictable and efficient review processes. The Center has made real progress in its efforts to improve these

processes. Much of the credit goes to leadership of CDRH. But constructive oversight and input from Congress, plus the engagement of industry and other stakeholders was and will continue to

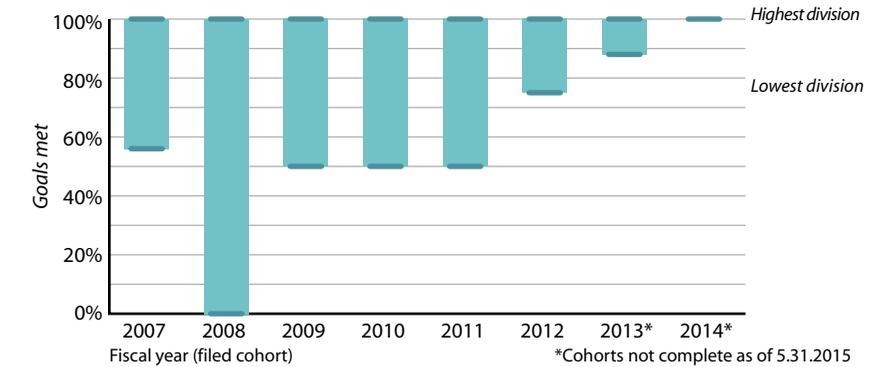
be critical. With the next round of device user fee discussions already underway, now is the time to preserve, sustain and enhance the progress we've witnessed in recent years.

Comparing Divisions

Over the years, there have been significant variations in performance across CDRH review divisions and branches. Fortunately, the data suggests recent overall performance improvements have also resulted in more consistent performance across the system.

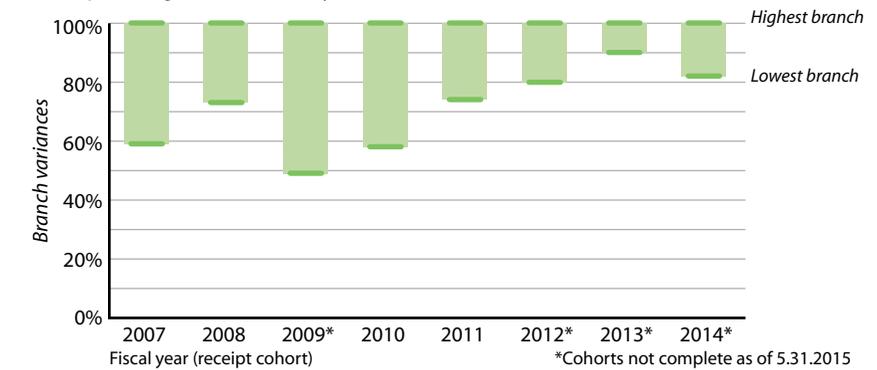
PMA MDUFA DECISIONS

Percentage variance meeting performance goals, fiscal years 2007-2014



510(k) FINAL DECISIONS MADE WITHIN 90 DAYS

Branch percentage variances, fiscal years 2007-2014



SOURCE: FDA data as of 5.31.15 and BCG Analysis

PAUL HORN

See methodology and more:
CALifeSciences.org/2015FDAUpdate
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