

# Medical Device Updates: U.S. Food and Drug Administration (FDA) Practice Trends

BY [BETHANY HILLS](#)

## **Data and Analytics — FDA's Post-market Surveillance Data Proposals Press Forward**

FDA's National Evaluation System for Health Technology, or NEST, as FDA calls it, is quickly gaining traction as one of the "game-changers" for the medical device industry. FDA has been working with stakeholders for years to develop a system to better monitor the long-term safety and effectiveness of medical devices. NEST proposes to use real-world device data, purporting to get devices to patients sooner in a regulatory paradigm that puts more emphasis on post-market data. This could mean less pre-market data needed for approvals, shifting the data review and analysis to the post-market setting. Certainly this paradigm shift will address the complaints around FDA's approval times and process, but there are significant concerns for a commercialization and approval strategy that shifts surveillance emphasis to post-market. Additional industry concerns include the sufficiency of the infrastructure, such as the lack of Unique Device Identifier codes reported on insurance claim forms.

Sen. Patty Murray, D-Wash., the ranking member of the Senate Health, Education, Labor and Pensions (HELP) Committee, has pressed the issue of strengthening device post-market surveillance (like the NEST program) during recent hearings focused on the HELP Committee's medical innovation package. And the NEST program is just one of the key initiatives central to the ongoing negotiations for the fourth iteration of the Medical Device User Fee Act (MDUFA IV), which begins in 2017.

FDA has emphasized the benefits of NEST, including reducing requests for post-approval studies in Premarket Approval Application (PMA) decisions and increased ways to monitor the quality of devices on the market. Although a launch of NEST is unlikely for another couple of years, we continue to evaluate the practical impact of the infrastructure development to gather the data, the central coordinating center to analyze the data, and the impact on device submissions and approvals. If FDA succeeds in obtaining industry funding for development of NEST in the MDUFA negotiations, device companies will need to begin analyzing the impact that different external data streams characterizing their devices' performance will have on their regulatory status with FDA.

## **Reimbursement Focus at FDA Continues**

It is no secret that achieving FDA approval of a device is only just the first step in successful commercialization of a medical device. The role of coverage and reimbursement is finally beginning to dominate the discussion in the U.S. The pilot FDA-CMS Parallel Review program did successfully result in a simultaneous approval/coverage determination under FDA and Medicare and Medicaid Services' (CMS) joint parallel review program. For example, CMS opened a national coverage determination for Exact Sciences' *Cologuard*, the first stool-based colorectal cancer screening test, on the same day FDA approved the test in 2014. However, the success of the formal program has been criticized for years. We've known for some time that FDA was pursuing an informal reimbursement initiative within the agency, seeking to encourage private payors to participate in pre-submission meetings prior to device approvals. In recent public meetings, Center for Devices and Radiological Health (CDRH) Director Jeffrey E. Shuren, M.D., J.D., confirmed that FDA has extended these invitations to payors to help the FDA and the industry better understand the evidence needed for positive coverage determinations and to attempt to align the FDA and reimbursement processes. FDA confirmed at the

Medical Device Manufacturers Association conference last May that, to date, no private payor has taken FDA up on the offer. CMS continues to struggle to find agency resources available to participate in FDA pre-approval discussions, although CMS representatives continue to express an interest in parallel review processes.

While involving the payor perspective early in the process is certainly something medical device innovators are considering internally when designing studies and engaging with the marketplace, whether that process should be formalized during the FDA review of a device remains uncertain. Device manufacturers continue to face the issue of private payors requesting data to substantiate coverage that differs, sometime significantly, from data presented to FDA in the approval process. Or worse, private payors limit coverage parameters based on FDA approval documents, highlighting the tension between a minimal FDA regulatory strategy and the desire for broader reimbursement coverage in the marketplace.

### **Unique Device Identifier (UDI) September 2016 Deadline Approaching**

Phase III of the UDI implementation requires the remaining Class III devices, those that are multi-use or to be reprocessed, and all Class II devices to bear a UDI and submit the required data by September 2016. Device companies are facing the practical challenge of needing to develop key aspects of their quality system to ensure a labeling system that meets the requirements and can handle the practicalities of adding this information to the label design and labeling process. Challenges include actually placing the UDI on the label, establishing the UDI on software devices and ensuring all of the data required to be submitted to the Global Unique Device Identification Database (GUDID) is gathered and reported, including data not only stemming from the label itself but from various locations across the organization. All device companies should be focused on integrating UDI into their quality process now. As noted above, the UDI field is increasingly becoming a focus of post-market surveillance data systems like NEST and will certainly become a central aspect of post-market safety and recall management.