# FDA's Center for Devices and Radiological Health Releases Its 2014-2015 Strategic Priorities

Emalee G. Murphy and Jordan C. Kearney

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) recently released its 2014-2015 Strategic Priorities. The Strategic Priorities are generally released annually, but this year, CDRH released a two-year plan. The Strategic Priorities provide insight into the areas that CDRH considers most important. CDRH's three listed goals for 2014-2015 are to (1) strengthen the clinical trials process, (2) strike the right balance between premarket and postmarket data collection, and (3) provide excellent customer service. Overall, the Strategic Priorities focus on the steps CDRH will be taking to get high-quality, safe, and effective devices to U.S. patients as quickly as possible. This Bulletin highlights some of the key points from the Strategic Plan.

1. **Strengthen the clinical trials process.**

   - CDRH's Plan encourages companies to conduct clinical studies in the U.S. "earlier in the device development process than has historically occurred." CDRH has implemented a pilot program to facilitate the early clinical evaluation of novel technologies, and it has implemented process changes to the Investigational Device Exemption (IDE) program. FDA has already seen "substantial impact" from the changes to the IDE program, namely:

     - The percentage of IDE submissions that received an approval decision authorizing study initiation within two IDE cycles increased from 46% in FY 2011 to 77% in FY 2013.
     - Median time to full study approval was reduced from 435 days to 174 days during that time period.

   - A related and important goal for CDRH in 2014 is to "improve the efficiency, consistency, and predictability of the IDE process to reduce the time and number of cycles needed to reach appropriate IDE full approval for medical devices, in general, and for devices of public health importance, in particular." Specifically, CDRH's targets are to:

     - Reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 25% by September 30, 2014 and by 50% by June 30, 2015.
     - By September 30, 2014, offer all sponsors of disapproved IDEs a teleconference or in-person meeting within 10 business days of the IDE decision.
     - Reduce further the overall median time to appropriate full IDE approval from 174 days to around 130 days by September 30, 2014 and to 30 days by June 30, 2015.

   - CDRH also seeks to "increase the number of early feasibility/first-in-human IDE studies submitted to FDA and conducted in the U.S."

2. **Strike the right balance between premarket and postmarket data collection.**

    - In 2014, CDRH will be looking to shift some of the premarket data requirements to the postmarket setting. This shift is in accordance with the Agency's obligation to use the least burdensome means for evaluating devices.

    - CDRH will begin to review all device types on the market to determine whether to shift some of the premarket data requirements to the postmarket setting or to pursue "down- classifications." CDRH's targets are to complete this process for 50% of device types by December 31, 2014, for 75% by June 30, 2015, and for 100% by December 31, 2015 and to communicate its decisions to the public.

3. **Provide excellent customer service.**

    - CDRH has prioritized its goal of meeting the following targets:

        - Achieve at least 70% customer satisfaction by December 31, 2014.
        - Achieve at least 80% customer satisfaction by June 30, 2015.
        - Achieve at least 90% customer satisfaction by December 31, 2015.

The Strategic Priorities do not address remaining issues related to premarket (510(k)) notification requirements; difficulties attributable to new and less experienced reviewers; or use of FDA's Refuse To Accept Policy for 510(k)'s as material reviews; all of which remain areas of concern.

## Authors and Contributors

**Emalee G. Murphy**
Of Counsel, DC Office
202.677.4052
emalee.murphy@agg.com

**Jordan C. Kearney**
Associate, Atlanta Office
404.873.8152
jordan.kearney@agg.com

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**Atlanta Office**
171 17th Street NW
Suite 2100
Atlanta, GA 30363

**Washington, DC Office**
1775 Pennsylvania Ave., NW,
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