Commissioner Agrees Industry Is No Beast of Burden; Provides Plan to Improve Least Burdensome Approach

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The concept of "least burdensome" review is not new. Starting with the FDA Modernization Act of 1997 (FDAMA), the Food and Drug Administration has been directed to take the "least burdensome approach" to the premarket evaluation of medical devices – i.e., to minimize unnecessary burdens to industry while maintaining the regulatory standards for clearance or approval of devices. What *is* new is FDA's updated commitment to focus on employing a "least burdensome" approach in its reviews. In response to a recent GAO report on FDA's implementation of the "least burdensome" requirements, FDA Commissioner Scott Gottlieb issued a statement explaining how FDA is modernizing its approach to medical device regulation.[1] Commissioner Gottlieb's statement echoes the themes of CDRH's 2018-2020 Strategic Priorities, which were also released in January 2018.[2]

According to Commissioner Gottlieb, "[a]n effective and consistent least burdensome approach is essential for evaluating novel devices under FDA review as well as accommodating iterative improvements to existing devices already on the market."[3] The GAO report concluded that FDA needs to "develop and use performance metrics to evaluate the implementation of the least burdensome requirements,"[4] and Commissioner Gottlieb agreed that this evaluation is needed. Commissioner Gottlieb pointed to a number of steps FDA has already taken to apply the "least burdensome" approach, as well as describing steps planned for the future:

- Expansion of the use of "real world data" gathered as part of clinical care (e.g., electronic health records and patient registries)
  - Issuing draft guidance in October 2017 on the Breakthrough Device Program to encourage manufacturers to communicate early and frequently with FDA[5]
  - Qualifying the first medical device development tool—a system that aims to provide standardized measurements/assessments of a device's risks and benefits early in the development process—in October 2017
- Training more than 90% of CDRH staff on the "least burdensome" requirements, with plans to audit the training in June 2018 (a requirement of the 21st Century Cures Act)
- Issuing a draft guidance in December 2017 to address the "least burdensome" requirements[6]
  - The draft guidance, when finalized, will supersede FDA's 2002 guidance on the same topic
- Outlining "different pathways" for manufacturers to engage with FDA earlier in the development process, especially in emerging areas like gene therapy, regenerative medicine, and 3-D printing

1 "Least Burdensome Medical Device Approvals," GAO-18-140, available at https://www.gao.gov/assets/690/689065.pdf. Statement from FDA Commissioner Scott Gottlieb, M.D., in response to GAO report regarding FDA's ongoing commitment to employing a least burdensome approach to device review, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592632.htm.

2 CDRH 2018-2020 Strategic Priorities are available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM592693.pdf.

3 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592632.htm.

4 https://www.gao.gov/assets/690/689065.pdf.

5 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

6 The draft guidance, when finalized, will supersede FDA's 2002 guidance on the same topic. Draft guidance available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf.

- Following a risk-based compliance approach to focus on higher-risk devices and make the development process more efficient
    - For example, FDA's general wellness guidance issued in 2016 clarified that FDA does not intend to examine low-risk fitness and wellness products
    - FDA is also "considering, in some narrow cases, complementary and voluntary new programs to encourage product developers to seek the benefits of FDA review through more efficient third-party validation and a new 'Pre-Cert' review process"
- Planning to propose an alternate approach to the traditional 510(k) pathway, involving science-based, consensus standards and FDA-developed performance criteria[7]

Commissioner Gottlieb also emphasized that FDA's "stringent review standards will not change"; this renewed focus on streamlining the review process does not change FDA's emphasis on patient safety. That said, the 2018-2020 CDRH Strategic Priorities make clear that FDA seeks to make device review and approval/clearance more efficient. The "Measure of Success" for this set of priorities is that "[b]y December 31, 2020, more than 50 percent of manufacturers of novel technologies for the U.S. market intend to bring their devices to the U.S. first or in parallel with other major markets."[8]

AGG Observations

- FDA's system for reviewing medical devices can make bringing an innovative device to market inherently challenging. If a product is not eligible for review under the 510(k) pathway, the process for generating additional required clinical data may deter manufacturers from attempting marketing in the U.S. first (prior to working with Notified Bodies in Europe). FDA's updated priorities make clear that FDA seeks to be the "first stop" for manufacturers of novel medical devices.

- 21st Century Cures requires FDA to reevaluate its application of the "least burdensome" requirements, and the standard also applies to significant decisions, meaning that FDA must explain how it considered these standards when, for example, denying a PMA application. Although FDA has been required to take a "least burdensome" approach for more than a few years, 21st Century Cures has added a level of accountability, which is reflected in Commissioner Gottlieb's statement touting the agency's recent and promised actions.

7 More information available at https://blogs.fda.gov/fdavoice/index.php/2017/12/new-steps-to-facilitate-beneficial-medical-device-innovation/.
8 https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM592693.pdf.

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