

## The Food and Drug Administration Safety and Innovation Act of 2012: Assessing the Impact on the Medical Device Industry



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**O**n July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).<sup>1</sup> The legislation, which stemmed from separate bills that made their way through both houses of Congress over the past several months, amends the Federal Food, Drug, and Cosmetic Act (FDCA) to reauthorize the Food and Drug Administration (FDA) user fee programs for drugs and medical devices through September 30, 2017. The law also creates new user fee programs for generic drugs and biosimilars, and enacts several Agency reforms aimed at improving various FDA regulatory processes and priorities, including the medical device review and approval processes. The law also includes several “Miscella-

neous Provisions” that will further affect FDA’s regulation of medical devices.

FDASIA was developed through an extensive two-year collaboration between FDA, industry, and the public, and the legislation generally enjoyed widespread support throughout the process, including bipartisan congressional sponsorship and consistent backing from the White House. This article provides an overview of the statute’s major medical device provisions and their anticipated impact on the regulated industry.

### **Medical Device User Fees**

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was enacted to enable user fee payments by the medical device industry to supplement congressional appropriations to FDA in return for Agency commitments to outlined performance goals.<sup>2</sup> These goals focused on more timely premarket reviews and increased FDA communication and guidance in the regulatory process. The Food and Drug Administration Amendments Act of 2007 enacted the Medical Device User Fee Amendments of 2007 (MDUFA II) as a reauthorization of the program along with the prescription drug user fee reauthorization and other regulatory reforms,<sup>3</sup> and the MDUFA framework has, over the last 10 years, allowed FDA to bring medical devices and di-

<sup>1</sup> Pub. L. No. 112-144, 126 Stat. 993.

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<sup>2</sup> Pub. L. No. 107-250, 116 Stat. 1588.

<sup>3</sup> Pub. L. No. 110-85, 121 Stat. 823.

agnostics to market more quickly.<sup>4</sup> MDUFA fees and mandated appropriations have also helped FDA expand available expertise, modernize its information management systems, provide new review options, and provide more guidance to prospective applicants.<sup>5</sup> However, the medical device premarket review process has faced increasing criticism in recent years for its alleged lack of transparency and consistency, which has resulted in considerable uncertainty for medical device developers and manufacturers.<sup>6</sup> As a result, MDUFA reauthorization, which must occur every five years to avoid the law's sunset provision, has been the subject of much negotiation between the Agency and regulated industry, producing significant commitments from FDA.

The Medical Device User Fee Amendments of 2012 (MDUFA III) contained in FDASIA authorize \$595 million in user fees over the next five years in return for significant changes in FDA performance and accountability. The fees are divided into two categories—premarket application fees and establishment registration fees—both of which are nearly doubled by the new legislation. Much of the increase in revenue for FDA will be attributable to an expansion of the types of establishments required to pay a FDA registration fee. Dr. Jeffrey Shuren, Director of FDA's Center for Devices and Radiological Health (CDRH), has cautioned that, unlike the PDUFA program which funds more than half of all drug and biologic reviews, user fees collected under MDUFA II in fiscal year 2010 funded only about 20% of the device review program.<sup>7</sup> The new increase in fees under MDUFA III will result in FDA having a harder time claiming that it lacks the resources necessary to fulfill its mandate.

**Premarket Application Fees.** MDUFA III prescribes the premarket approval application (PMA) fee amount each fiscal year, also referred to as the "base fee." User fees for other submission types are calculated based on a prescribed percentage of the PMA fee identified in the FDCA: panel track supplements are 75% of the PMA fee; 180-day supplements are 15%; real-time supplements are 7%; 30-day notices are 1.6%; efficacy supplements are equal to the PMA fee; 501(k)s are 1.84%; re-

quests for classification information are 1.35%; and periodic reporting concerning a Class III device is 3.5%. Under MDUFA III, the PMA fees for the five-year period (to be adjusted for inflation and subject to a reduction for small businesses) are as follows:

Fiscal Year	PMA Fee
2013	\$248,000
2014	\$252,960
2015	\$258,019
2016	\$263,180
2017	\$268,443

**Establishment Registration Fees.** MDUFA III expands the types of establishments that are subject to a user fee. Under the new legislation, any establishment that is registered or is required to register with FDA because it is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is subject to user fees. Previously, only those establishments that were required to register with FDA and that were "manufacturers," "single-use device processors," or "specification developers" were subject to the fee. Under MDUFA III, the establishment registration fees for the five-year period (to be adjusted for inflation) are as follows:

Fiscal Year	Registration Fee
2013	\$2,575
2014	\$3,200
2015	\$3,750
2016	\$3,872
2017	\$3,872

In return for the increased fees, FDA has agreed to a number of meaningful performance goals outlined in its commitment letter to Congress.<sup>8</sup>

**Process Improvements.**

- **Pre-Submissions:** FDA has committed to instituting a structured process for managing pre-submissions, i.e., formal written requests for feedback from FDA prior to an applicant's submission of an investigational device exemption (IDE) or marketing application. The Agency committed to issuing a draft guidance document on pre-submissions, which was released on July 12, 2012.<sup>9</sup> The performance goals specify timeframes for pre-submission meetings and teleconferences, and the guidance assists applicants by clarifying when to submit pre-submissions and what they

<sup>4</sup> *FDA User Fees 2012: How Innovation Helps Patients and Jobs*, Hearing before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 112th Cong. 2 (2012) (statement of Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health) [hereinafter *FDA User Fees*], available at <http://republicans.energycommerce.house.gov/Media/file/Hearings/Health/20120418/HHRG-112-IF14-WState-ShurenJ-20120418.pdf>.

<sup>5</sup> *Id.*

<sup>6</sup> See, e.g., John R. Manthei, Ben Haas & Rebecca Brandt, *Medical Device Reform Is (Almost) Here: FDA Announces Action Items for Improving the Agency's 510(k) Premarket Clearance Program*, BNA MED. DEVICES L. & INDUSTRY REP. (Mar. 9, 2011) (5 MELR 170, 3/9/11) (describing the outcomes of two FDA task forces convened to review and propose changes to the 510(k) program to address "critical challenges facing the Center and [its] external constituencies").

<sup>7</sup> *FDA User Fees*, at 2.

<sup>8</sup> FDA, *MDUFA Performance Goals and Procedures* (Apr. 18, 2012), <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf>.

<sup>9</sup> FDA, *Draft Guidance for Industry and FDA Staff: Medical Devices: The Pre-Submission Program and Meetings with FDA Staff* (July 13, 2012), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf> (6 MELR 467, 7/25/12).

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should contain. Importantly, the performance goals make clear that FDA intends that the feedback the Agency provides will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in an applicant's pre-submission and the data in the future submission do not raise any important new issues materially affecting safety or effectiveness. FDA has agreed that modifications to FDA's feedback will be limited to situations in which FDA concludes, with appropriate management concurrence, that the feedback does not adequately address important new issues materially relevant to a determination of safety or effectiveness.

- **Submission Acceptance Criteria:** FDA has committed to implementing revised submission acceptance criteria, including guidance outlining electronic copies of submissions and objective criteria for revised "refused to accept/refuse to file" checklists. FDA released its guidance on acceptance and filing review for PMAs on July 31, 2012, and its guidance on the new refuse to accept policy for 510(k)s on August 10, 2012.<sup>10</sup>
- **Interactive Review:** FDA has committed to continue to provide for, and encourage, informal communication between FDA and applicants, including the exchange of scientific and regulatory information, to facilitate timely completion of the review process based on accurate and complete information.
- **Guidance Document Development:** FDA has agreed to apply user fee revenues to supplement the improvement of the process of developing, reviewing, tracking, issuing, and updating guidance documents, but not to the detriment of meeting quantitative review timelines and statutory obligations. In particular, FDA has committed to updating its website in a timely manner to delete guidance documents that no longer represent the Agency's current thinking, to publish an "A-list" of prioritized device guidance documents that FDA will publish in the 12 months following publication of the list, and to publish a "B-list" of device guidance documents that FDA will publish as its guidance-development resources permit each fiscal year. FDA will also establish a process to permit stakeholders to provide comments and suggestions on the proposed lists.
- **Third-Party Review:** FDA has agreed to continue to support its third-party review program and establish new procedures to improve transparency as resources permit.

<sup>10</sup> FDA, *Draft Guidance for Industry and Food and Drug Administration Staff: Acceptance and Filing Review for Pre-market Approval Applications (PMAs)* (July 31, 2012), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368.pdf> (6 MELR 494, 8/8/12); and FDA, *Draft Guidance for Industry and Food and Drug Administration Staff: Refuse to Accept Policy for 510(k)s* (Aug. 13, 2012), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

- **Patient Safety and Risk Tolerance:** FDA has committed to fully implementing its final guidance on the factors to consider when making benefit-risk determinations in medical device premarket reviews.<sup>11</sup> Such factors include patient tolerance for risk, magnitude of benefit, and availability of other treatments or diagnostic tests. The guidance includes commitments from FDA to require its PMA and de novo petition reviewers to use a benefit-risk determination worksheet in all of their reviews which will become part of the administrative record.<sup>12</sup>
- **Low-Risk Medical Device Exemptions:** By the end of fiscal year 2013, FDA has agreed to propose exemptions from premarket notification for additional low-risk medical devices.
- **Emerging Diagnostics:** FDA has agreed to work with industry to develop a transitional *in vitro* diagnostic (IVD) device approach for the regulation of emerging diagnostics.

#### **Review Performance Goals.**

- **PMAs, Panel-Track Supplements, and Premarket Report Applications:** FDA has agreed to communicate whether an application has been accepted for filing within 15 days of receipt and issue a decision within 180 days if advisory committee input is not required, or 320 days if it is required, for 50% of submissions in fiscal year 2013, increasing each year to 90% in 2016–2017. For PMA submissions that do not reach a decision by 20 days after the applicable goal, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the application.
- **180-Day PMA Supplements:** FDA has agreed to issue a decision within 180 days for 85% of submissions in fiscal year 2013, increasing each year to 95% in fiscal 2016–2017. For real-time PMA supplements, FDA will issue a decision within 90 days for 90% of submissions in 2013–2014 and 95% in 2015–2017. Finally, for 510(k) submissions, FDA has agreed to communicate whether a 510(k) has been accepted for review within 15 days and issue a decision within 90 days for 91% of fiscal year 2013 submissions, 93% of 2014 submissions, and 95% of 2015–2017 submissions. For 510(k) submissions that do not reach a decision within 100 days, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the submission.
- **No Moving Goalposts:** In an important reform for industry, FDA has agreed that when the Agency issues a major deficiency letter in a PMA review, or

<sup>11</sup> FDA, *Guidance for Industry and Food and Drug Administration Staff: Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications* (Mar. 28, 2012), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM296379.pdf> (6 MELR 215, 4/4/12).

<sup>12</sup> See generally Ben Haas, Elizabeth Richards & Amy Gaither, *Client Alert: Medical Device Benefit-Risk Determinations: FDA Releases a Novel Guidance Giving Industry and Inside View of Agency Decision-Making* (Apr. 12, 2012).

when it identifies deficiencies in a substantive interaction or an additional information letter in a 510(k) review, the letter or communication will be based on a complete review of an applicant's submission and will include all deficiencies. Any subsequent deficiencies identified by FDA will be limited to issues raised by the information provided in the applicant's response to FDA's letter or communication, unless FDA concludes that the initial deficiencies identified do not adequately address important new issues materially relevant to a determination of safety or effectiveness for PMAs, or substantial equivalence for 510(k)s. Such a determination must be supported by the appropriate management concurrence.

**Shared Outcome Goals.** The performance goals commitment letter makes clear that FDA and applicants share the responsibility for achieving the objective of reducing the average total time to decision while maintaining standards for safety and effectiveness. To that end, beginning in fiscal year 2013, FDA will report on an annual basis the average total time to decision for PMAs and 510(k)s. For fiscal year 2013, the average total time to decision goal for PMAs is 395 calendar days, reduced to 390 days in 2015 and 385 days in 2017. Likewise, for fiscal year 2013, the goal for 510(k)s is 135 calendar days, reduced to 130 days in 2015 and 124 days in 2017.

**Infrastructure Goals.** FDA has agreed to apply user fee revenues to reduce the ratio of review staff to front line supervisors in the premarket review program and to enhance and supplement scientific review capacity by hiring device application reviewers and leveraging external experts needed to assist with the review of device applications. The Agency has also agreed to certain staff training goals, including implementing its Reviewer Certification Program and holding a minimum of two Vendor Days per year. FDA will also continue its efforts to improve its information technology systems with the future expectation of real-time status availability for device submissions.

**Independent Assessment of Review Process Management.** As an important performance goal to industry, FDA has agreed to participate with industry in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry, and will be conducted under contract by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required. The assessment will address FDA's premarket review process using a framework that draws from appropriate quality system standards, including management responsibility, document controls and records management, and corrective and preventative action. FDA has committed to incorporating the findings and recommendations into its management of the premarket review program as appropriate.

**Performance Reports.** As with all user fee programs, FDA must report to Congress on its progress in achieving its agreed-upon commitments. The performance goals commitment letter outlines FDA's reporting timeline commitments, along with details on the additional information the Agency has agreed to provide on an annual basis.

## Medical Device Regulatory Improvements

A major industry initiative in the user fee negotiations of the past two years was to obtain certain regulatory improvements to clarify FDA authority, streamline Agency procedures, and pave a transparent path to market for new medical devices. After years of increased scrutiny for CDRH, many of the final legislation's changes have been widely supported by the regulated industry.<sup>13</sup> Others have been praised by consumer safety advocates, though some claim the provisions do not go far enough to ensure device safety.<sup>14</sup> Moreover, there were some notable proposals that were ultimately not included in the final legislation, including for example, proposals pertaining to predicate device nullification and conditional clearance authority for FDA. On the whole, the improvements are perceived to represent a winning compromise among stakeholders; they include the following provisions:

- **Investigational Device Exemptions.** In recent years, FDA has utilized an informal policy that has generally limited approval of IDEs to those investigational studies that will support a PMA submission or that would be necessary for a substantial equivalence determination. One of the key concerns in FDA's application of this policy is its potential to limit innovation and device development. Section 601 of FDASIA confirms that FDA is bound to approve IDEs based on the standards enumerated in the FDCA and FDA regulations. As amended by FDASIA, the FDCA now explicitly precludes FDA from denying an IDE on the basis that a proposed investigation may not support a 510(k) or PMA or that additional or different investigations may be necessary to support clearance or approval.
- **Clarification of the Least Burdensome Standard.** Section 602 of the Act amends the FDCA to help define the term "necessary" in the context of the statute's least burdensome requirements for premarket review.<sup>15</sup> The Act clarifies this requirement by adding language to define the term "necessary" as "the minimum required information that would support a determination" that a PMA provides a reasonable assurance of effectiveness or that a 510(k) supports a determination of substantial equivalence, thereby reaffirming the least burdensome approach while defining one of its key terms. This language does not change the standards for evaluating PMAs or 510(k)s, but clarifies the threshold for "least burdensome" in the context of premarket reviews and ultimately is aimed at preventing FDA's requests for information on data that might be pertinent or interesting

<sup>13</sup> See, e.g., House Energy & Commerce Committee, "Fact Sheets: Stakeholders Support of the FDA Reform Act," <http://energycommerce.house.gov/news/PRArticle.aspx?NewsID=9518> (last visited June 29, 2012).

<sup>14</sup> See, e.g., Letter from Lisa McGiffert & Lisa Swirsky, Consumers Union Safe Patient Project, to Hon. Tom Harkin, Hon. Michael Enzi, Hon. Fred Upton & Hon. Henry Waxman (June 7, 2012), [http://safepatientproject.org/wp-content/uploads/2012/06/MDUFA\\_conf\\_comm\\_612.pdf](http://safepatientproject.org/wp-content/uploads/2012/06/MDUFA_conf_comm_612.pdf).

<sup>15</sup> See FDCA § 513(a)(3)(D)(ii), 513(i)(1)(D).

to the review but not essential to clearance or approval.

- **Agency Documentation and Review of Significant Decisions.** Section 603 of the Act adds a new requirement to the FDCA in Section 517A, that requires CDRH to provide a substantive summary of the scientific and regulatory rationale for any significant decision regarding an IDE, 510(k), or PMA submission, including documentation of significant controversies or differences of opinion and their resolutions.<sup>16</sup> Importantly, this new statutory requirement does not define “significant decision.” CDRH must furnish this summary to the submitter upon request, and any person, including submitters and Agency personnel, may request an expedited supervisory review of the significant decision, with an in-person or teleconference meeting if desired. Although there is some vagueness in the timing triggers for requesting a review, the general timeframes Section 603 creates for requesting and FDA providing a review include that: (i) an applicant may request an in-person or teleconference meeting within 30 days of the decision; (ii) the meeting on the review should occur within 30 days of the request; and (iii) if a meeting is requested, FDA has 30 days after the request or the meeting to issue its decision on the review, and if no meeting is requested, FDA has 45 days.
- **Device Modifications Requiring Premarket Notification Prior to Marketing.** Pursuant to FDA’s regulatory requirements, manufacturers must submit a new 510(k) for a previously cleared device if the device is changed or modified and that change “could significantly affect safety or effectiveness” or “constitute[s] a major change or modification in intended use.”<sup>17</sup> FDA has provided two different guidance documents intended to assist industry in making a determination as to when a new 510(k) is required for a change or modification to a device.<sup>18</sup> The most recent of these guidance documents was issued in draft form in July 2011 and proposed what appeared to be significant changes to the decision-making framework.<sup>19</sup>

<sup>16</sup> FDA released a final guidance in March 2012 committing its PMA and de novo petition reviewers to using a benefit-risk determination worksheet in all of their reviews, and making the worksheet part of the administrative record. See *supra* notes 11–12. This provision of the FDA Safety and Innovation Act takes the commitment one step further by, among other requirements, mandating a documented rationale for all types of applications and significant decisions within the medical device review cycle.

<sup>17</sup> 21 C.F.R. § 807.81(a)(3).

<sup>18</sup> FDA, *Guidance for Industry and FDA Staff: 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device: Draft Guidance* (July 27, 2011) (5 MELR 479, 7/27/11) (withdrawn); FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device* (Jan. 10, 1997), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf>.

<sup>19</sup> See generally Carolyne Hathaway, John Manthei, Rebecca Brandt & Elizabeth Richards, *A Guide to FDA’s Draft Guidance on 510(k)s*, MASS DEVICE (Oct. 19, 2011) (“Although the FDA has suggested that the new guidance does not change

Section 604 of the Act requires FDA to withdraw the controversial July 2011 draft guidance, which it did on July 17, 2012. Additionally, within the next 18 months, FDA must prepare and submit a report to Congress providing FDA’s interpretation of several key terms including definitions of “could significantly affect the safety or effectiveness of the device,” “a significant change or modification in design, material, chemical composition, energy source, or manufacturing process,” and “major change or modification in the intended use of the device.” In preparing the report, FDASIA requires FDA to consider the input of industry. Although FDA may issue a draft guidance after providing the report to Congress, FDA is prohibited from issuing a final guidance or proposed regulation that addresses the topic until one year after the report’s submission. In the meantime, FDASIA confirms that the FDA’s 1997 guidance document will continue in effect.

- **Program to Improve the Device Recall System.** Section 604 of FDASIA requires FDA to establish a program to routinely and systematically assess information relating to device recalls and use this information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. The Act further requires FDA to clarify device recall audit check procedures, develop detailed criteria for assessing recall corrective action plans, and document the basis for each device recall termination.
- **Clinical Holds on Investigational Device Exemptions.** Section 606 of the Act grants FDA new authority to issue a clinical hold prohibiting an IDE sponsor from conducting an investigation if FDA determines that the device involved represents an unreasonable risk to the safety of the subjects of the investigation. In making a determination to issue a clinical hold, the new statutory provision requires FDA to take into account the qualifications of the clinical investigator, the health status of the study participants, and the condition being treated. FDA may also establish other reasons for issuing a clinical hold by regulation. The Act affords the investigation sponsor the right to submit a written request to FDA to remove the clinical hold, but the sponsor bears the burden of submitting sufficient information to support the removal. FDA must respond in writing to a written request to remove a clinical hold within 30 days.
- **Modification of De Novo Application Process.** Under the pre-FDASIA de novo classification process, FDA was required to issue a not-substantially-equivalent (NSE) determination for a 510(k) submission, automatically placing the device in Class III, before the device sponsor could submit a de novo petition to request that the device be down-classified to Class I or II due to its low or moderate risk.<sup>20</sup> Section 607 of FDASIA modifies and streamlines the de novo process by

its current policy or practice regarding submission of 510(k)s for modified devices, it is estimated that, if finalized in its current form, the Draft Guidance will increase the number of modified devices requiring 510(k)s.”)

<sup>20</sup> FDCA § 513(f)(2).

permitting low- or moderate-risk device sponsors to submit a de novo classification request to FDA without first submitting a 510(k) and receiving an NSE determination. Under this new process, in order to submit a de novo classification request to FDA, the applicant must first determine that there is no legally marketed predicate device for purposes of establishing substantial equivalence. The applicant may then submit a de novo petition, including a recommended classification for the device and, if applicable, an initial draft of any special controls that may be necessary. FDA has 120 days to classify the device or deny the de novo process to the device either because it is not low- or moderate-risk or there is a predicate device upon which the Agency can base its review.

- **Reclassification Procedures.** Section 608 of FDASIA permits FDA to change the classification of a device by administrative order instead of by regulation based on new information regarding the device. In issuing the reclassification administrative order, FDA may also revoke any related regulation or requirement in effect under a PMA approval order. To utilize this new power, FDA must hold a reclassification panel meeting for review of the action and must consider industry comments. FDA must also publish the proposed reclassification in the Federal Register and provide a substantive summary of the valid scientific evidence concerning the proposed reclassification. The proposed order must explain why special controls are not sufficient to assure the safety and effectiveness of the device for an up-classification order or why they are sufficient for a down-classification order, and must include certain enumerated types of evidence. The Director of CDRH, in consultation with the Commissioner of FDA, is required to issue the reclassification order, and the Agency is required to provide an annual reporting of its reclassification orders on its website.
- **Harmonization of Device Premarket Review, Inspection, and Labeling Symbols.** Section 609 of FDASIA authorizes FDA to enter into arrangements with foreign countries on harmonizing regulatory requirements, including those regarding inspections and common international labeling symbols.
- **Participation in International Fora.** The U.S. Department of Health and Human Services Office of International Relations is currently permitted to participate in meetings with representatives of other foreign governments to work toward harmonized regulatory requirements. Section 610 of FDASIA clarifies that FDA has the authority to participate in appropriate fora, including the International Medical Device Regulators Forum, and provide transparency on such international activities. Specifically, FDA may (i) provide guidance on strategies, policies, directions, membership, and other activities; (ii) solicit, review, and consider comments from industry, academia, health care professionals, and patient groups regarding the fora's activities; and (iii) inform the public of FDA's activities with any fora, sharing documentation as appropriate.
- **Reauthorization of Third-Party Review and Inspection.** Sections 611 and 612 of FDASIA reauthorize the third-party review and third-party inspection programs, under which FDA may accredit third parties to perform medical device reviews and establishment inspections, through October 1, 2017. In addition, the Act establishes that an accreditation is only valid for three years after issuance. The revised language requires FDA to approve or deny a reaccreditation request no later than 60 days after receiving the request. FDA is required to publish criteria to reaccredit or deny reaccreditation by November 6, 2012.
- **Humanitarian Device Exemptions.** The FDCA permits FDA to approve a device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year without the benefit of data demonstrating the device is effective for its intended use.<sup>21</sup> Generally, however, manufacturers with devices approved under the humanitarian device exemption (HDE) are precluded from profiting from sales of HDE devices. Under current HDE requirements, FDA may grant an exemption from the prohibition on profit for devices intended for use in pediatric patients. Section 613 of FDASIA expands this exemption to include HDE devices intended for use in adults if the device is intended to treat a disease or condition that does not occur in pediatric patients, or that occurs in such numbers that the device's pediatric development is impossible, highly impracticable, or unsafe. Additionally, the annual distribution number for HDE devices permitted to be sold at a profit is set at the amount of devices needed to treat 4,000 individuals in the United States during any calendar year unless the FDA grants a request to modify the annual distribution number.
- **Unique Device Identifier.** Section 614 of FDASIA requires FDA to issue proposed regulations establishing the unique device identification (UDI) system required under the last user fee reauthorization no later than December 31, 2012, finalize the regulation within six months of the comment period closing, and implement the system for implantable, life-saving, and life-sustaining devices within two years after the regulations are finalized, taking into account patient access to medical devices and therapies. FDA released the proposed UDI regulations on July 10, 2012.<sup>22</sup> The comment period closes on November 7, 2012 which means that, pursuant to the new statutory timelines, the UDI regulations should be finalized in May 2013.
- **Sentinel.** Sentinel is a national electronic system under development by FDA that will enable the Agency to query diverse automated healthcare data holders in order to proactively evaluate and mitigate possible post-market medical product

<sup>21</sup> See FDCA § 520(m).

<sup>22</sup> Unique Device Identification System, 77 Fed. Reg. 40,736 (July 10, 2012) (6 MELR 442, 7/11/12).

safety issues.<sup>23</sup> Section 615 of FDASIA requires FDA to extend the Sentinel system to 510(k)-cleared and PMA-approved medical devices and to engage outside stakeholders to help ensure effective implementation of the system with respect to devices.

- **Postmarket Surveillance.** Section 616 of FDASIA clarifies that FDA has the authority to order a sponsor to conduct post-market surveillance under Section 522 of the FDCA for any Class II or Class III device by clarifying that FDA may issue such an order either at the time of approval or clearance, or at any time thereafter. Sponsors must also now commence such surveillance no later than 15 months after the date of FDA's order.
- **Custom Devices.** Although the FDCA and FDA have historically recognized and permitted custom devices, Section 617 of FDASIA establishes new definitions and requirements for permitted custom devices. As amended by FDASIA, the FDCA now requires that custom devices be created or modified to comply with an individual physician or dentist order (or other qualified person designated by FDA regulations), that the order require the device to deviate from applicable performance standards, and that the device not be generally available in the United States in finished form. Moreover, although the device must be furnished on a case-by-case basis, the device may have common design characteristics or common manufacturing processes as the associated commercially available device. This legal framework for custom devices, which exempts them from all premarket requirements, is restricted to apply only to devices that are created for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations would be impractical. The manufacturer of such a device must also now limit production to under five units per year of a particular device type, and must also notify FDA of its custom device manufacturing. FDA is required to issue final guidance on these revised custom device exemptions by July 9, 2014.
- **Health Information Technology.** Section 618 of FDASIA requires FDA to work with the National Coordinator for Health Information Technology and the Chairman of the Federal Communications Commission to issue a report by January 9, 2014 on a proposed risk-based regulatory framework pertaining to health information technology, including mobile medical applications.<sup>24</sup> This regulatory framework should promote innovation, protect patient safety, and avoid regulatory duplication, and the working group must include external stakeholders and experts in addition to the individuals from the other regulatory agencies.

<sup>23</sup> See FDCA § 505(k)(3)(C); FDA, *FDA's Sentinel Initiative*, <http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm> (last visited June 29, 2012).

<sup>24</sup> FDA issued a guidance document and convened a public meeting on mobile medical applications in 2011, but the Agency's current stance on the topic, and health information technology in general, remains vague and uncertain. See Ben Haas, *FDA Regulation of E-Health Technology and Services*, in *E-HEALTH, PRIVACY, AND SECURITY LAW* (W. Andrew H. Gantt III ed., 2d ed. 2011).

- **Good Guidance Practices Relating to Devices.** Section 619 FDASIA amends the FDCA to clarify that a notice to industry guidance letter, a notice to industry advisory letter, and any similar notice that sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, should be treated as an FDA guidance document. By clarifying that these letters and agency interpretations are guidance documents, the Act confirms that these communications are subject to FDA's good guidance practice rules. As a result, industry and stakeholders should generally be afforded an opportunity to comment on proposals for these "guidance documents" before they become effective or are implemented by the Agency.
- **Pediatric Device Consortia.** Section 620 of FDASIA reauthorizes the demonstration grant program for nonprofit consortia to promote pediatric device development. However, this reauthorization reduces the amount of the previous authorization level. FDA is also required to issue a proposed regulation by December 31, 2012 and a final rule by December 31, 2013 implementing the requirement for pediatric use device applications to include a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, and the number of affected pediatric patients.

### **Additional Amendments and Provisions Pertinent to the Medical Device Industry**

The final title of FDASIA contains several provisions aimed at miscellaneous Agency reforms. Some of the more significant provisions impacting the medical device industry include the following:

- Section 1121 requires FDA to issue guidance describing its policy regarding Internet and social media promotion of regulated medical products by July 2014.
- Section 1123 explicitly authorizes FDA to work with foreign regulatory authorities, medical research companies, and international organizations to foster uniform, scientifically driven global clinical trial standards. Under the provision, FDA must enhance its commitment to providing parallel scientific advice for manufacturers seeking simultaneous global development of medical products by facilitating the use of foreign data in FDA regulatory submissions and minimizing the need for sponsors to conduct duplicative studies. FDA is also now required to accept data from international clinical investigations during its review of medical product applications if the data are adequate to support product approval.<sup>25</sup>

<sup>25</sup> FDA has implemented policies accepting foreign clinical trial data under certain circumstances, but the new legislative mandate requiring it to do so is likely to increase instances where FDA will accept such data, and may also increase the requirements foreign clinical trials must meet. See generally Carolyne Hathaway & Anne Hanson, *Client Alert: FDA Offers New Guidance on Acceptance of Foreign Clinical Trials* (Apr. 23, 2012).

- Section 1124 requires FDA to develop a strategy and implementation plan for advancing regulatory science for medical products by July 2013 and submit annual performance reports on its progress.
- Section 1137 instructs FDA to solicit the views of patients during the medical product development and review process and consider the perspectives of patients during regulatory decision-making. FDA must utilize a patient representative to serve as a special government employee in appropriate agency meetings and explore ways to identify patient representatives who have little or no financial interests in the medical products industry.
- Section 1138 requires FDA to develop a communication plan to inform and educate healthcare providers and patients on the benefits and risks of medical products, with a particular focus on underrepresented subpopulations, including racial subgroups, by July 2013.
- Section 1142 provides FDA with greater flexibility under its conflict of interest rules to fill advisory committee vacancies with experts who have a financial interest that could be affected by the advice given to FDA, provided that FDA adequately discloses the nature of the interest and reports annually to Congress regarding advisory committee membership. The provision calls for FDA to develop and implement strategies for effective outreach, advertising, and recruitment efforts, as well as disclose the type, nature, and magnitude of advisory committee members' financial interests at least 15 days before a committee meeting. FDA must also issue a guidance document on FDA's review of financial interests.
- Section 1143 prohibits FDA from issuing guidance on the regulation of laboratory developed tests

(LDTs), a subset of IVD devices, unless it provides Congress with details of the proposed regulation at least 60 days in advance.<sup>26</sup>

## **Conclusion**

Though there were many controversial proposals associated with the FDASIA legislation, most of which did not make it into the final statute, the user fee bills nonetheless enjoyed consistent support from the majority of public stakeholders through the development process, as well as backing from the White House, which lauded the bipartisan effort. FDASIA was considered “must pass” legislation, as both the prescription drug and medical device user fee program statutes were set to expire this October without reauthorization. Many of the legislative reforms confirm or clarify the scope of FDA’s authority and require FDA to continue working with industry to successfully implement the medical device provisions. As a result, FDA and industry must now begin the onerous task of understanding, and implementing, those provisions.

<sup>26</sup> Although LDTs fall under FDA’s medical device purview, the Agency historically employed its enforcement discretion to refrain from actively regulating them. In 2010, however, FDA began to express interest in establishing a regulatory framework for LDTs, which was met with strong industry opposition. The Agency has yet to follow through with its plans. See generally Carolyne Hathaway, John Manthei & Elizabeth Richards, *The Changing Regulatory Landscape for In Vitro Diagnostic Medical Devices: Increased Scrutiny of Laboratory Developed Tests and the Safety of Personalized Medicine*, FOOD & DRUG LAW INST. UPDATE (September/October 2010) (“[O]pponents of greater FDA oversight of LDTs have cited concerns that the costs and burden of obtaining FDA approval or clearance are likely to stifle innovation in a field that holds the promise of personalized medicine. . . .”).