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NO SUMMER VACATION FOR DEVICE REGULATORS: AN OVERVIEW OF RECENT LEGISLATION AND FDA ACTIVITY, PART II

In Part I of this *Commentary*, presented in a separate publication, we summarized some of the new legislation recently promulgated by Congress in the Food and Drug Administration Safety and Innovation Act ("FDASIA"). We scanned the newly expanded user fee provisions for applicants and registrants, and the FDA's complementary "MDUFA III Commitment Letter." We described some of the developments stemming from both the FDASIA and the FDA's initiatives—affecting investigational device exemptions ("IDEs"), clinical trials, premarket approval applications ("PMAs"), and 510(k) submissions.

In this Part II, we will continue our overview of the FDASIA, focusing on some of the stand-alone and special provisions dealing with humanitarian and custom devices and the accredited and special persons who are authorized to assist the FDA with its duties. However, we will resume our discussion with the FDA's initiatives, starting with perhaps the most controversial—the newly proposed rules relating to unique device identification ("UDI").

THE FDA'S NEW (AND NOT SO NEW) INITIATIVES

Unique Device Identification Rules. At present, there is no final regulation specifically mandating a universal system for identifying medical devices. For some time, however, Congress (and the FDA) have suggested that such a system would provide numerous benefits to the public, fundamentally reducing medical errors caused by the misidentification of devices or their properties. A system of this nature, they say, would simplify the databases used to collect information about medical devices, make them more user friendly, and make it easier to associate adverse event reports with specific devices. This in turn would facilitate remedial actions such as earlier warnings,

appropriate safety bulletins, and recalls of potentially defective products. Also, a universal identification system would increase the FDA's ability to monitor trends, create reports, and perform more sophisticated analyses.[1]

In 2007, Congress instructed the FDA to "promulgate regulations establishing a unique device identification system for medical devices."[2] But before this summer's passage of the FDASIA, the FDA had yet to propose any rules. Thus, an impatient Congress imposed strict deadlines on the FDA: (i) by December 31, 2012, the FDA must propose such regulations; (ii) within six months after the close of the comment period on those proposed regulations, the FDA must finalize those regulations; and (iii) within two years from that point, the FDA must implement the regulations with regard to certain devices.[3] This time, the FDA responded.

Just one day after the FDASIA was signed into law, the FDA proposed the unique device identification regulations,[4] a rather protracted set of rules that run for almost 11 pages in the Federal Register. In short, the FDA's proposal provides:

- A UDI will be composed of two parts:
  - a device identifier, identifying the specific version or model of a device and its labeler; and
  - one or more of the lot or batch number, the serial number of the specific device, the expiration date, or the manufacturing date.
- With exceptions, every device will be required to have a UDI on its label and on its package.
- Some devices will be required to have the UDI marked directly upon the device itself.
- The UDI will be presented both in ordinary text and in a machine-readable format.
- The UDI will be referenced when submitting reports to the FDA, such as adverse event reports, annual reports, and reports of corrections and removals.
- The labeler of a device will be required to submit additional information to the FDA so that the FDA's "Global Unique Device Identification Database" could cross-reference a UDI against an array of information about the device.

Comments on these proposed rules are due by November 7, 2012.

The UDI rules are part of a broader push by the FDA to strengthen its post-marketing surveillance. A new FDA white paper showcases four linked FDA initiatives. In addition to establishing the UDI system, the FDA intends: (i) to promote the development of national and international device registries for selected products; (ii) to modernize adverse event reporting and analysis; and (iii) to develop and use new methods for evidence generation, synthesis, and appraisal.[5]

Health Information Technology. In addition to providing the FDA with new tools, the rapid advancement of information technology poses a substantial challenge for the FDA. Indeed, new technology allows for a very rapid increase in the number, types, and sophistication of medical devices. The FDA must keep abreast of this advancing technology and appropriately balance the goals of patient safety against "the discovery and development of useful devices intended for human use."[6] As part of this effort, last year the FDA issued an important draft guidance discussing how it intends to regulate "mobile medical apps."[7]

In the FDASIA, Congress instructs the FDA to further study these technology issues and to issue a report "that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication."[8] The report is due in January 2014.[9]

Recalls and Surveillance. Even without its new initiatives, the FDA has had strong remedies available to address defective or unreasonably risky devices. Indeed, the FDA has long had the power to order manufacturers to issue notices of dangerous conditions; to offer to repair, replace, or refund the purchase price of an unsafe device; and, of course, to recall it altogether.[10]

Through the FDASIA, Congress has called upon the FDA to improve the device recall system by identifying practical strategies to mitigate harm from defective or unsafe devices and by clarifying its procedures for auditing a manufacturer's recall obligations. The FDA must release detailed criteria that would be used to assess whether a recall has been

properly conducted, and the FDA must document any decision to terminate a device recall.[11]

The FDA can also order a manufacturer to conduct postmarket surveillance for certain Class II and Class III devices.[12] The FDASIA expands (or at least clarifies) that authority by allowing the FDA to issue such an order, not just at the time of approval or clearance but also "at any time thereafter."[13] If the FDA orders surveillance, the surveillance must begin within 15 months of the order.[14]

SPECIAL PROVISIONS OF THE FDASIA

Humanitarian Devices. Congress expanded the conditions under which a manufacturer may sell humanitarian devices at a profit. Sales revenue from humanitarian devices is generally restricted to the amount necessary to recoup "the costs of research and development, fabrication, and distribution of the device."[15] An exception existed for devices that could be used to treat children and were sold in limited number.[16]

Under the FDASIA, humanitarian devices intended only for adults may now also be sold at a profit, as long as the disease that the device treats or addresses does not afflict children. Similarly, such devices for adults may be sold when the disease to be treated by the device is so rare that the device cannot be developed for pediatric patients.[17] The new legislation also adds flexibility to the procedure for asking the FDA to modify the number of devices that can be sold without voiding the ability to sell at a profit.[18]

Custom Devices. In the FDASIA, Congress significantly tightened the definition of "custom devices" that would be exempt from premarket approval requirements and from performance standards.[19] Previously, a device qualified as a "custom device" if it was intended to respond to the needs of an individual patient or physician and was not generally available to or generally used by other physicians or doctors.[20] The FDASIA, however, adds a surplus of new requirements that must be met to qualify a device as "custom." First, no more than five such devices can be produced per year. Second, each device created must be in order to comply with a doctor's orders (on a case-by-case basis). Third, the device must "necessarily deviate" from the premarket approval rules or performance standards. Finally, the device must treat a "unique pathology" for which no other device is available, and the condition treated is "sufficiently rare" to render clinical investigations impractical.[21]

Procedural Rules Applicable to Guidance Documents. The promulgation of guidance documents is itself a highly regulated endeavor. Since 1997, the FDA has been under instructions to issue guidance documents, to invite public participation in the drafting process, and to refrain from deviating from guidance documents without cause.[22] The FDASIA clarifies that the FDA may not circumvent this rule by issuing informal letters entitled "notice to industry." Any such informal notices relating to devices will be treated as guidance documents.[23]

Outside Reviewers and Inspectors. The FDASIA also amends a few of the regulations pertaining to who may participate or assist in the application and review process. Existing law provides that the FDA can rely on non-employees ("accredited persons") to make recommendations regarding the clearance of most devices subject to the 510(k) process and regarding the initial classification of devices.[24] The FDASIA reauthorizes the program for another five years[25] and further clarifies the process of reaccrediting "accredited persons."[26]

The FDASIA also reauthorizes another program important to the FDA—the non-employee inspector program.[27] Similar to the "accredited persons" program, the FDA may rely on non-employees to inspect device establishments, and the FDASIA likewise extends this program for another five years.[28]

CONCLUSION

While the user fee amendments stole the summer headlines, the FDASIA and new the FDA pronouncements have a far broader impact. Thanks to Congress and the FDA's summertime activities, there are many changes to the governing device regulations that warrant awareness and compliance.

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ENDNOTES

1 77 FD 40736-37 (July 10, 2012).

2 FD&C Act, § 519(f) (as enacted by Food and Drug Administration Amendments Act).

3 FDASIA, § 614.

4 77 FR 40735 (July 10, 2012).

5 FDA, *Strengthening Our National System For Medical Device Postmarket Surveillance* (September 2012).

6 21 C.F.R. §812.1(a). The quoted regulation only applies directly to the IDE process, but the goal applies across CDRH's programs. *See* CDRH Mission, Vision, and Shared Values.

7 FDA, *Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications* (July 21, 2011). For a detailed discussion of this guidance, see Jones Day Commentary, "Is Your Smart Phone an FDA-Regulated Medical Device?" (August 2011).

8 FDASIA, § 618(a).

9 *See id.*

10 FD&C Act, § 518.

11 FDASIA, § 605.

12 FD&C Act, § 522(a).

13 FDASIA, § 616(1).

14 FDASIA, § 616(2).

15 FD&C Act, § 520(m)(3).

16 FD&C Act, § 520(m)(6)(A).

17 FDASIA, § 613(a).

18 *Id.*

19 FD&C Act, § 520(b).

20 *Id.*

21 FDASIA, § 617.

22 FD&C Act, § 701(h).

23 FDASIA, § 619.

24 FD&C Act, § 523(a)(1).

25 FDASIA, § 611(b).

26 FDASIA, § 611(a).

27 FDASIA, § 612.

28 FD&C Act, § 704(g).