KING & SPALDING

Client Alert

Healthcare Practice Group

August 31, 2017

President Trump Signs FDA User Fee Reauthorization Bill into Law – A Relief for the Medical Device Industry

On August 18, 2017, in the nick of time, President Trump signed the FDA User Fee Reauthorization Bill of 2017 (FDARA) (H.R. 2430) into law, bringing a sigh of relief from both FDA and Industry.[1] The law reauthorizes the Prescription Drug User Fee Act (PDUFA) for the fifth time, the Medical Device User Fee Amendments (MDUFA) for the third time, and both the Generic Drug User Fee Amendments (GDUFA) and the Biosimilar User Fee Act (BsUFA) for the first time. FDARA reauthorizes the user fee legislations through FY 2022. Without reauthorization, FDA's ability to collect user fees would have expired on September 30, 2017, and over 5,000 FDA employees would have lost their jobs, severely impacting Agency operations.[2]

FDA and Industry are both praising the bipartisan effort. James C. Greenwood, President and CEO of the Biotechnology Innovation Organization (BIO), called the legislation a "historic achievement."[3] In a recent "tweet," Scott Gottlieb, FDA Commissioner, thanked the House for passing FDARA, saying it is "key for FDA, patients."[4] FDARA's impact on the medical device industry extends beyond just reauthorizing MDUFA. It specifically (1) directs FDA to implement new inspection policies, which also provide greater flexibility for obtaining Certificates for Foreign Governments (CFGs), (2) incentivizes the development of pediatric devices, (3) creates a more flexible path to market for certain new medical device accessories, (4) establishes a category of over-the-counter hearing aids, (5) fosters innovation in medical imaging devices that use contrast agents, and (6) requires FDA to establish voluntary postmarket surveillance pilot projects. This client alert summarizes these key provisions and others that will impact the medical device industry.

MDUFA Reauthorized Until FY 2022

FDARA maintains a similar fee calculation structure, however, for the first time, the statute requires FDA to apply an inflation adjustment to the user fee every year, including FY 2018. FDARA, § 203(c). The new base amounts and total revenue amounts for the next five (5) years are provided below.

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Fee Type	*FY 2018*	*FY 2019*	*FY 2020*	*FY 2021*	*FY 2022*
Premarket Application Base Fee	$294,000	$300,000	$310,00	$328,000	$329,000
Establishment Registration Base Fee	$4,375	$4,548	$4,760	$4,975	$4,978
Total Revenue Amount	$183,280,756	$190,654,875	$200,132,014	$211,748,789	$213,687,660

Over the next five (5) years, the total fee amount will increase to over $999.5 million, plus inflation. The increased fees will come largely from increasing the facility registration fees – facility fees will increase from around $3,382 (FY17) to around $4,375 (FY18). The premarket application base fee will increase from $268,443 (FY17) to $294,000 (FY18).

Additionally, FDARA significantly increases the user fees for some submissions. Previously, de novo classification request were not subjected to user fees, however, FDARA establishes user fees for de novo classification requests. The base fee for a de novo classification request is 30 percent of the pre-market application base fee, or $88,200 in FY 2018. FDARA, § 203(a). Additionally, the base fee for a 510(k) premarket notification submission will increase from 2 percent of the premarket application base fee to 3.4 percent of the premarket application base fee. As a result, the 510(k) premarket notification submission base fee will increase from $4,690 (FY17) to $9,996 (FY18).

Conversely, small businesses – those whose gross receipts or sales were $100 million or less on their most recent Federal income tax return, including such returns of all of their affiliates – will pay less percentage wise. FDARA § 203(e) requires small businesses to pay 25 percent of the 510(k) premarket notification submission fee rather than 50 percent of the 510(k) Premarket Notification submission fee, as in years past. For small businesses, the 510(k) Premarket Notification submission base fee is $2,499 in FY18.

Establishes New Inspection and Enforcement Policies

Title VII of FDARA, "Device Inspection and Regulatory Improvements," hopes to make inspections more predictable and consistent. These improvements are intended to provide greater transparency between FDA and Industry, and to improve communication between FDA investigators and the inspected firm during and after the inspection.

- *Directs FDA to Implement a Risk-Based Schedule for Device Establishment Inspections*

FDARA § 701(a) requires FDA to inspect establishments engaged in the manufacture, propagation, or processing of a device in accordance with a risk-based schedule established by FDA. The new risk-based schedule for devices will be influenced by: the establishment's compliance history; whether the establishment has prior device recalls; inherent risk of the device being manufactured; inspection frequency and history, including whether the establishment has been inspected within the last four (4) years; whether the establishment has been inspected by a foreign government; and participation of the establishment in international device audit programs. The new risk-

based schedule replaces the current statutory requirement that Class II and III device establishments be inspected every two (2) years.

- *Directs FDA to Update and Adopt Uniform Device Inspection "Processes and Standards" for Routine Inspections*

FDARA § 702(a) requires FDA to review and update its "processes and standards" related to inspection of domestic and foreign device establishments to establish uniform processes and standards. Such uniform processes and standards must include: exceptions to processes and standards; notification to firm of an upcoming routine inspection "within a reasonable time before such inspection occurs;" an opportunity for advance communication before inspection to discuss inspection logistics and records that will be requested; a reasonable estimate of the timeframe for the inspection; and regular communication during the inspection regarding the inspection status.

Additionally, FDARA § 702(b) requires FDA to issue draft guidance by February 18, 2019, that addresses the device inspection processes and standards; standard methods for communication; standard timeframes for foreign and domestic device inspections; and practices "to facilitate the continuity of inspections."

- *FDA Required to Provide Feedback on Firm's Proposed Corrective Actions following issuance of FDA-483*

A firm that receives a Form FDA-483 may request feedback on its proposed corrective action if the request is timely and the proposed corrective actions involve a public health priority, systemic or major actions at the establishment, or an emerging safety issue. FDARA, § 702(a). FDA must respond to such request within forty-five (45) days with nonbinding feedback, although the statute is silent on how FDA must respond (i.e. whether the response can be written or oral).

- *Devices are Deemed Adulterated if Manufacturer Delays, Denies, or Limits an Inspection, or Refuses to Permit Entry or Inspection at the Site*

21 U.S.C. § 351(j) deems a drug adulterated if it "has been manufactured, processed, packed, or held in any factory, warehouse, or establishment [where] the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection." FDARA § 702(c) revises this provision to include medical devices in addition to drugs. The provision was originally added in 2012 as part of the FDA Science and Innovation Act (FDASIA).

- *Establishes a Pathway by which Manufacturers Denied a Certificate to Foreign Governments (CFG) Can Work with FDA and Resolve the Issue*

Under FDA's statute, device manufacturers that export devices may obtain a Certificate to Foreign Governments (CFG) from the Agency. This certificate indicates that the device is not adulterated or misbranded because it (1) meets foreign specifications and the laws of the foreign government, and (2) is in compliance with the FDA statute. FDARA § 704 requires FDA to establish a pathway by which manufacturers denied a CFG based upon a significant FDA-483 can work with FDA and resolve the issues. By statute, FDA must now describe in writing the basis for denying a CFG, and the Agency cannot deny a CFG simply because the firm received a 483 observation if the firm has "agreed to a plan of correction." Once a firm is denied a CFG, the firm shall be able to request that FDA review the denial in lieu of new information relating to action taken to address the reasons for the denial. FDA must provide additional guidance as to how a firm can request review of a CFG denial in a guidance document that must be issue by August 18, 2018. Note that these provisions apply to both domestic and foreign establishments. However, for the provision to apply to a request by a foreign establishment whose devices are not to be exported

from the United States, the foreign establishment must have been inspected by FDA or audited by an audit program recognized by the United States within three (3) years of the time of the request.

- *Increases FDA's Ability to Conduct Audits Through Recognized Auditors (Including Foreign Auditors)*

FDARA § 705 allows FDA to recognize auditors used by foreign governments to improve international harmonization of inspection standards and increase FDA access to audit data. Additionally, FDARA § 703 reauthorizes FDA's authority to conduct inspections via accredited organizations through 2022.

Incentives for the Development of Pediatric Devices

FDARA attempts to expand access to pediatric devices. First, § 502(b) incentivizes the development of pediatric devices by reauthorizing statutory exemptions that allow a manufacturer of a pediatric device approved under the Humanitarian Device pathway to sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device until October 2022. To qualify for the exemption, among other qualifications, the device must be intended for, and labeled for, use in pediatric patients or in a pediatric subpopulation, and must be intended for the treatment or diagnosis of a disease or condition that is rare in the pediatric population so the development of the device for pediatric patients is impossible, impracticable, or unsafe. 21 U.S.C. § 360j(m)(6)(a)(iv).

Second, § 502(b) extends access to humanitarian devices by allowing "an appropriate local committee" to approve the use of a humanitarian device. Prior to FDARA, an institutional review committee would need to approve the use of a humanitarian device before it could be used. Now, either an appropriate local committee or an institutional review committee can approve the use of such devices.

Third, § 502(d) requires FDA to hold a public meeting to discuss the development, approval, or clearance and labeling of pediatric medical devices no later than August 18, 2018. The meeting is required to cover topics such as research infrastructure, post-market registries and data to support pediatric medical device labeling, how FDA can assist manufacturers in developing devices for pediatric populations, and other barriers to pediatric device development. Following the meeting, FDA will summarize the meeting, including any recommendations raised in the meeting.

Establishes a Flexible Pathway to Market Medical Device Accessories

FDARA provides a process for classifying and reclassifying medical device accessories to implement the provision in the 21st Century Cures Act that requires FDA to classify an accessory based on its own risks, rather than the classification of the device with which such an accessory is to be used with. Under FDARA, an applicant can request that FDA classify the device and the accessory separately, even if the applicant filed a single premarket approval ("PMA") or 510(k) for both the device and the accessory. FDARA, § 707(a). Previously, if an applicant sought PMA approval or 510(k) clearance for a device and accessory in a single application, FDA would classify the device and accessory together, leading to many over classifications of accessories.

For accessories already classified, the manufacturer or importer can request an appropriate classification based on the risk and appropriate level of regulatory control for that accessory. FDA must respond to the request within eighty-five (85) calendar days by issuing a written order classifying the device accessory or denying the request. FDA will publish any reclassification in the Federal Register within thirty (30) days. Additionally, within a year, and every five (5) years thereafter, FDA must publish in the Federal Register a proposed list of accessories that

FDA determines may be suitable for classification into Class I. This new process should present an avenue to deregulate some lower risk accessories.

Establishes a New Category of Over-the-Counter Hearing Aids

FDARA creates a category of over-the-counter (OTC) hearing aids intended to be used by adults eighteen (18) years or older to compensate for mild to moderate hearing impairment. FDA must promulgate proposed regulations establishing the new category of OTC hearing aids before August 2020. FDARA, § 709(b). The regulations must provide reasonable assurance of the safety and effectiveness of these devices, provide the requirements for labeling, and provide a determination about whether OTC hearing aids require a 510(k) premarket notification. Additionally, FDA must update and finalize its guidance distinguishing hearing aid devices and personal sound amplification products. FDARA, § 709(c). FDARA preempts any state law that restricts or interferes with the sale of OTC hearing aids. FDARA § 709(b)(4).

Fosters Innovation in Medical Imaging as It Relates to Contrast Agents

FDARA clarifies that FDA has the authority to approve PMAs or clear 510(k)s for a new imaging device that uses an approved contrast agent in a way not approved in the contrast agent's labeling. Specifically, FDA can consider approving or clearing a new imaging device that uses a contrast agent that is not (1) in a concentration, rate of administration, or route of administration that is in the approved labeling of the contrast agent, (2) in a region, organ, or system of the body that is in the approved labeling of the contrast agent, or (3) in a patient population that is different from those described in the contrast agent's approved labeling. FDARA, § 706(a). Additionally, § 706(b) allows the sponsor of a contrast agent, in some cases, to submit a supplement to its application to update its labeling once FDA approves or clears a new imaging device that uses the contrast agent in a new way. Collectively, these provisions will allow industry to keep up with the significant advances in medical imaging equipment and spur further innovation.

Requires One or More Pilot Projects to Improve Postmarket Surveillance

FDARA requires FDA to initiate one or more pilot projects designed to improve the time and reliability of information gathered on the safety and effectiveness of devices, and to develop methods, systems, and data criteria that support active surveillances. These projects will request voluntary participation from device manufacturers and may evaluate electronic health data, such as claim data and patient survey data. FDARA § 708(a) also authorizes FDA to continue and expand any similar postmarket surveillance projects already underway. FDA may meet its obligation by contracting with public or private entities that meet certain criteria.

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King & Spalding is experienced in responding to FDA warning letters and FDA-483 observations, conducting audits of quality systems, representing clients before FDA on enforcement issues, and assisting clients with the submission of device marketing applications. Our team would be pleased to assist life sciences companies and investors with understanding the implications of the FDA User Fee Reauthorization Bill of 2017 as it applies to specific practices or products. Our team also has significant experience shaping policy at FDA and at the congressional level, and we would be pleased to assist interested parties as they continue to work with FDA to implement the regulations and guidance documents required by FDARA.

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[1] *H.R. 2430 – FDA Reauthorization Act of 2017*, CONGRESS.GOV, https://www.congress.gov/bill/115th-congress/house-bill/2430/actions (last visited Aug. 28, 2017).
[2] Sarah Karlin-Smith, *Price pushes Congress to follow Trump plan for more FDA user fees*, POLITICO (May 17, 2017), *available at* http://www.politico.com/story/2017/05/17/price-pushes-lawmakers-to-follow-trumps-plan-for-more-fda-user-fees-less-taxpayer-funding-238508.
[3] *BIO Applauds Signing of Food and Drug Administration Reauthorization Act (FDARA)*, Business Wire (Aug. 18, 2017), http://www.businesswire.com/news/home/20170818005605/en/BIO-Applauds-Signing-Food-Drug-Administration-Reauthorization.
[4] Scott Gottlieb, TWITTER (July 12, 2017), *available at* https://twitter.com/SGottliebFDA/status/885208875884040194.