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Client Alert Commentary

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FDA Announces Planned Changes to the 510(k) Premarket Notification Program

Agency signals forthcoming changes that could impact manufacturers' ability to commercialize new medical devices.

Background

On November 26, 2018, officials from the Food and Drug Administration (FDA or the Agency) and the Center for Devices and Radiological Health (CDRH) announced a series of forthcoming steps FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) (the 510(k) program). In its announcement, FDA also flagged that it plans to propose new regulations clarifying procedures and requirements for submissions under the *de novo* pathway.[1]

The announcement reflects FDA's broader efforts intended to improve and modernize the medical device regulatory framework and to promote regulatory efficiency, including reforms under its Medical Device Safety Action Plan issued in April 2018 and its Digital Health Innovation Action Plan issued in August 2017.[2] To that end, as part of the announcement, FDA also made available a "performance report"[3] detailing measures taken by the Agency over the past decade to improve the 510(k) program, with a focus on these recent efforts.

In announcing its policy proposals, the Agency provided notice of its plans to take specific actions to reform the 510(k) program, including with respect to the use of predicates and post-market surveillance, as well as the potential for FDA to seek additional guidance from Congress. In each instance, these developments provide the opportunity for direct stakeholder engagement with the Agency, and the potential for interaction with legislators regarding proposed changes to the 510(k) and *de novo* programs.

Promoting the Use of Newer Predicates

FDA Commissioner Scott Gottlieb, MD, and CDRH Director Jeff Shuren, MD, who issued the announcement, called for the 510(k) framework "to be modernized to reflect advances in technology, safety and the capabilities of a new generation of medical devices."[4] The announcement reflects the Agency's focus on innovation by driving manufacturers utilizing the 510(k) program toward the use of newer predicates. FDA pointed to the fact that 20% of 510(k)s are cleared based on a predicate that is more than 10 years old, and the Agency espoused its belief that new devices should not be compared

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with older predicate devices that "might not closely reflect the modern technology embedded in new devices"[5] or a more current understanding of the benefits and risks of the device.

FDA's announcement outlines a number of steps that the Agency plans to take to encourage the use of more recent predicates by manufacturers. First, FDA announced that it plans to develop "proposals to potentially sunset certain older predicates."[6] While the Agency did not clarify the scope of or cite authority for its proposal to "sunset" 510(k)-cleared predicates, it noted it may need to interact with Congress on these plans. The Agency also highlighted the fact that it will consider whether the "sunsetting" approach should become a requirement in the future. Importantly, FDA stated in its announcement that it does not believe devices that rely on old predicates are unsafe, or that older devices need to be removed from the market, indicating that any "sunsetting" proposal may be limited to a restriction on the use of such older devices as predicates, rather than a proposal to remove such older devices from the market. The announcement does not indicate a particular time when FDA plans to develop or publicize the details of its "sunsetting" proposals.

FDA also announced that it is considering publishing on CDRH's website "in the next few months" those devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. This proposal also lacks details critical to industry and other stakeholders. For instance, FDA does not indicate whether it proposes to implement such a policy on a going-forward or retrospective basis, or whether FDA would limit publication to those devices for which the predicate was more than 10 years old at the time of clearance or whether such publication would include cleared devices for which the predicate has since become greater than ten years old. The format and content of such a publication also remains unclear. Indeed, FDA already maintains a public database of releasable 510(k)-cleared devices, which often contains a device's summary review identifying its respective predicate(s).

Notably, however, FDA clarified that prior to any such publication, it intends to seek public feedback on whether the Agency should proceed with its plan to publicly identify those devices or those manufacturers of technologies that rely on predicates that are more than 10 years old, and whether other criteria should inform the Agency's approach. FDA also announced that it will seek public feedback on whether the Agency should take other actions to promote the use of more modern predicates.

Promoting an Alternative Route to 510(k) Clearance, the "Safety and Performance Based Pathway"

In connection with FDA's efforts to promote newer predicates, FDA also announced that it intends to finalize guidance in early 2019 to establish an alternative 510(k) pathway for "manufacturers of certain well-understood device types."[7] This new, alternative pathway, which FDA refers to as the "Safety and Performance Based Pathway," would allow manufacturers to rely on objective safety and performance criteria recognized by FDA to demonstrate substantial equivalence, and it would obviate the need for manufacturers to compare the safety and performance of their devices to a specific (and potentially old) predicate device in seeking 510(k) clearance.[8]

FDA stated in its announcement that this approach is intended to reflect a "contemporary baseline" for safety and effectiveness.[9] The Agency has previously indicated that it believes that such an approach may foster market competition to develop safer devices by allowing manufacturers to more readily demonstrate that their devices perform better than other devices under FDA-recognized standard performance and testing measures.[10] FDA expects this approach will benefit manufacturers in part by allowing them to readily demonstrate to payors that their products perform better than other devices on the market for the purposes of supporting coverage decisions.

Request for New Tools to Address Post-Market Surveillance Signals for 510(k)-Cleared Devices

FDA's announcement also touted the Agency's efforts to identify and act upon post-market safety signals related to medical devices. Specifically, the Agency noted that it has worked to eliminate the use of 510(k)-cleared devices as predicates in future 510(k) submissions when safety concerns have been identified that warranted their up-classification to Class III devices.[11] FDA has also imposed special controls on the basis of identified safety concerns. However, FDA's announcement raised concerns about significant limitations to both of these approaches. Specifically, FDA noted that the processes for up-classification and implementation of special controls are time and resource-intensive, do not contemplate the cross-cutting nature of some safety issues that must be addressed across device types, and do not allow FDA to take the swift action that is often necessary to address time-sensitive safety concerns. While FDA acknowledged that it often resorts to corresponding with manufacturers directly to address such issues on a voluntary basis, it declared its belief that it needs additional tools in its regulatory arsenal to address patient safety. FDA announced its plan to engage with Congress and stakeholders to develop proposals to address these concerns and expand its regulatory authority.

Impact on *De Novo* Submissions

FDA also indicated that, as a consequence of its proposed changes to the 510(k) program, it expected an increase in the use of the *de novo* pathway to market. To that end, FDA announced that, "in the next few weeks," it would issue a Notice of Proposed Rulemaking (NPRM) that will clarify procedures and requirements for *de novo* classification submissions.[12] However, the announcement otherwise provided little indication of the content of the proposed rule.

It is unclear whether FDA anticipates that increased use of the *de novo* pathway would stem from FDA's policy proposals limiting the ability to use older predicate devices, due to FDA's continued focus on post-market safety surveillance driving ineligibility of certain devices to serve as predicates, or for some other reason. However, the announcement implies that certain devices that may currently be eligible for clearance through the 510(k) process might need to be reviewed instead through the *de novo* classification pathway as a result of FDA's efforts intended to modernize the 510(k) program.

Takeaways and Next Steps

FDA has signaled that it intends to pursue comprehensive reforms to both the current 510(k) program and its post-market safety authorities, which could impact manufacturers' ability to obtain or maintain 510(k) clearance or other premarket authorizations to commercialize a new medical device. Although the precise form and content of FDA's 510(k) program modernization efforts remains uncertain, this announcement demonstrates Commissioner Gottlieb's continued focus on regulatory efficiency and modernization in the regulation of medical devices.

Industry and other stakeholders should continue to monitor the initiatives identified in FDA's announcement, including:

- FDA's proposals to "sunset" the use of older predicates and to publish a list of devices cleared using older predicates
- The planned issuance of a final guidance in early 2019 to establish an alternative 510(k) pathway for "well-understood" devices relying on objective safety and performance criteria
- FDA's proposals for enhanced post-market safety and surveillance authorities

- A new proposed rule for *de novo* classification submissions

Industry would also be well-advised to monitor congressional action in this space, as FDA acknowledges that certain of its proposals may require close coordination with Congress and the potential for legislative solutions.

This regulatory reform effort presents stakeholders an opportunity for meaningful engagement with both FDA and Congress to shape the future of premarket review of medical devices as the Agency moves forward to further develop and refine its proposals.

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Endnotes

[1] The *de novo* pathway is an alternate path to market for novel low-to-moderate risk medical devices for which there is no legally marketed predicate device.

[2] *See* FDA, Medical Device Safety Action Plan: Protection Patients, Promoting Health, available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf [hereinafter Medical Device Safety Action Plan]; FDA, Digital Health Innovation Action Plan, available at https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf.

[3] FDA, FDA Has Taken Steps to Strengthen the 510(k) Program, Nov. 2018, available at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM626541.pdf [hereinafter 510(k) Performance Report].

[4] FDA, Statement from FDA Commissioner Scott Gottlieb, MD, and Jeff Shuren, MD, Director of the Center for Devices and Radiological Health, on transformative new steps to modernize FDA's 510(k) program to advance the review of the safety and effectiveness of medical devices, Nov. 26, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm [hereinafter 510(k) Modernization Announcement].

[5] 510(k) Modernization Announcement.

[6] 510(k) Modernization Announcement.

[7] 510(k) Modernization Announcement.

[8] In the 510(k) Modernization Announcement, FDA described the alternative pathway as having been discussed in its Medical Device Safety Action Plan. The Medical Device Safety Action plan refers to a 2018 draft guidance document, *Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria*, which outlined an expansion of the Abbreviated 510(k) program to permit manufacturers to demonstrate a device's equivalent or superior performance to one or more legally marketed devices of its type, by virtue of conformance to objective performance criteria recognized by FDA. *See* Medical Device Safety Action Plan, at 12; FDA, Draft Guidance for Industry and Food and Drug Administration: Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria, at 7-8, Apr. 12, 2018, available at https://www.regulations.gov/document?D=FDA-2018-D-1387-0002.

[9] 510(k) Modernization Announcement.

[10] *See* Medical Device Safety Action Plan, at 12.

[11] FDA has taken action to up-classify 1,758 devices since 1976, with 84% of those taking place since 2012 alone. *See* 510(k) Performance Report, at 8.

[12] The Fall 2018 Unified Agenda of Regulatory and Deregulatory Actions (the Unified Agenda) identified FDA's plan to issue a proposed rule regarding the "Medical Device De Novo Classification Process" in October 2018, though as FDA acknowledges in the 510(k) Modernization Announcement, such proposed rule has not yet been issued. According to the Unified Agenda, the proposed rule "would establish procedures and criteria for the de novo process and would make it more transparent and predictable for manufacturers." OMB, Medical Device De Novo Classification Process, available at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0910-AH53 (last accessed 11/27/2018).