

MedTech update 2020 – Legal and regulatory issues to watch for in the medical technology industry in the new year: FDA regulatory developments

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Medical device and diagnostics companies and laboratories should anticipate significant legal, regulatory and market changes in 2020 that will have a lasting impact on the industry. From revisions to how the government regulates value-based care, to shifts in the marketplace for medtech mergers and acquisitions (M&A), 2020 will prove to be another year of evolution.

Based on recent trends and developments, Akin Gump attorneys have prepared several articles to provide the medtech industry with a landscape overview of the following issues in the year ahead: Food and Drug Administration regulatory developments; federal health care programs; international trade; intellectual property (IP) litigation; False Claims Act enforcement and health information and privacy and data protection.

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We plan to monitor and report on these developments and potential updates as the year unfolds.

FDA REGULATORY DEVELOPMENTS

FDA to continue reforms to premarket review pathways.

Across the globe, countries are revamping their regulatory oversight of medical technologies.

The European Union is implementing the new European Medical Device Regulation (MDR), which governs the manufacture and distribution of medical devices in Europe and takes a life-cycle approach to product regulation.

India very recently extended regulatory oversight to all medical devices that did not already require registration for marketing in the country, and China, in late 2017, issued 36 “Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices.”

The U.S. Food and Drug Administration (FDA) is not standing pat, either.

In 2020, FDA will continue advancing new approaches to premarket review, particularly for novel device technologies.

- *Software Pre-Certification Pilot Program (Pre-Cert)*: FDA’s concept for the future regulation of software as a medical device (SaMD) emphasizes oversight of the developer’s record of quality and organizational excellence with a focus on real-world performance, in exchange for greater flexibility for the software to evolve without need for supplemental reviews of new iterations. Pre-Cert 1.0, the first “test phase” version, is currently underway for pilot testing for certain SaMD developers.¹ Ultimately, the goal for this test phase is to determine whether the results of the Pre-Cert pathway align with the results of the traditional premarket pathway and satisfy FDA’s regulatory requirements for safety and effectiveness, and whether Pre-Cert can be implemented under FDA’s current regulatory authorities. In 2020, FDA will continue to test the Pre-Cert model and release updates that will hopefully provide more granular insights into the contours of a future Pre-Cert program for SaMD.
- *Artificial Intelligence (AI) and Machine Learning (ML)*: FDA’s 2019 white paper on medical software employing AI or ML,² which Akin Gump analyzed when it was released,³ introduced important terminology, including a core distinction between “locked” and “adaptive” algorithms, and contemplated the use of change protocols for leveraging AI/ML to advance SaMD tools. In the new year, FDA is likely to take tentative steps to advance these concepts in the context of individual SaMD clearances and approvals before establishing formal policies (or, alternatively, determining that legislation is required); companies leveraging AI/ML should consider advancing specific proposals for the use of change protocols.
- *Alternative 510(k) Pathway*: In 2019, FDA issued guidance establishing a Safety and Performance Based Pathway, which

is an offshoot of the Abbreviated 510(k) program for certain well-understood device types. Once this pathway is operationalized, a manufacturer of a 510(k) eligible device would be able to obtain clearance by meeting FDA-identified performance criteria to demonstrate substantial equivalence, rather than through a direct comparison to a predicate device.⁴ In September 2019, FDA issued several draft guidances identifying performance criteria and testing methodologies for certain devices within four class II device types. Expect further development of this pathway in the coming year.

- *Safer Technologies Program:* FDA also introduced the Safer Technologies Program (or STeP) via draft guidance in September,⁵ which is intended for finalization and implementation in 2020. STeP will provide expedited development support for devices and device-led combination products that are expected to improve the safety of currently available treatments or diagnostics, but that are not eligible for the Breakthrough Device pathway because they are intended for morbidities and mortalities less serious than Breakthrough-eligible devices.

FDA's evolving postmarket expectations.

Postmarket oversight of devices at FDA has undergone dramatic restructuring, through the development of product-specific inspection cadres under the agency's Program Alignment and through the reorganization of the Center for Devices and Radiological Health, to embrace a "total product life cycle" approach to device oversight.

In early 2019, FDA began raising concerns about pharmacogenomics information related to how a patient is likely to respond to a particular medication.

While these changes have coincided with a longer historical trend of a decrease in the use of warning letters, FDA's

postmarket oversight has not waned, and, in fact, has become more intensive in certain respects.

- *Safety Communications:* In recent years, the agency has placed increased emphasis on emerging signals, or information that substantiates or suggests associations between a marketed device and an adverse event, and the role these signals should play in postmarket surveillance. FDA issued guidance in late 2016 detailing what circumstances would warrant public release of emerging signals information. Overall, however, confusion remains about how such information is validated and used, and how it relates to existing tools to address potential safety issues. Stakeholders should be on the lookout for a public meeting or additional clarification on this topic in the first half of 2020.
- *Pharmacogenomics:* FDA has taken an aggressive stance on pharmacogenomics claims made by test developers and software developers. In early 2019, FDA began raising concerns about pharmacogenomics information related to how a patient is likely to respond to a particular medication. FDA issued a warning letter to one laboratory that refused to omit such information from its test reports. Akin Gump issued a client alert⁶ on this development at the time. FDA has expressed concerns with pharmacogenomics claims that are not supported by approved drug labeling and are not otherwise clinically validated.⁷ Given that pharmacogenomic information is heavily relied upon in the clinical community, expect to see continued focus on these claims, and FDA's expectations for substantiating them, in 2020.

Notes

¹ See U.S. Food and Drug Administration, Digital Health Software Precertification (Pre-Cert) Program, <https://bit.ly/2HgXuWP>.
² See U.S. Food and Drug Administration, Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device: Discussion Paper and Request for Feedback (April 2019), <https://bit.ly/2uGfJOC>.
³ <https://bit.ly/38nozlr>
⁴ See U.S. Food and Drug Administration, Guidance, Safety and Performance Based Pathway (Sept. 2019), <https://bit.ly/2tTxqth>.

⁵ See U.S. Food and Drug Administration, Draft Guidance, Safer Technologies Program for Medical Devices (Sept. 2019), <https://bit.ly/2SkqK0G>.

⁶ <https://bit.ly/2tWodAq>

⁷ See U.S. Food and Drug Administration, Direct-to-Consumer Tests, <https://bit.ly/2SFaxSD>.

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