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Pressure On Medtech Companies High, And Recalls Frequent, Amidst COVID-19

by

Medical device manufacturers are operating in what may be the industry's most challenging business and regulatory environment in recent history, attorneys Bill McConagha and Pamela Amaechi argue in this guest article.

As medtech companies work to meet the increased demand for critical equipment and personal protection equipment (PPE) caused by the COVID-19 pandemic, they find themselves operating in what may be the industry's most challenging business and regulatory environment in recent history.

The US Food and Drug Administration has devoted an immense amount of time and energy to support the COVID-19 response, and much of its initial focus on using the emergency-use pathway to bring essential devices to the front lines has been augmented by recent efforts to rid the market of underperforming or illegal products.

About The Authors

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To this end, the FDA has prioritized identifying and removing COVID-19 related products that appear to be unsafe. After concerns surfaced about the quality of Chinese-manufactured respirators, for example, the agency pulled a number of products from its list of authorized respirators for health care providers. State emergency response agencies pursued similar action, implementing recalls of masks issued to police and first responders.

> *"The regulatory landscape for medical devices is as complex as ever."*

In addition, the FDA acted against a number of diagnostic tests that failed to meet its efficacy threshold. Many such tests have been associated with a high rate of false negatives, which could lead patients to mistakenly believe they are not infected and risk exposing others.

At the same time, recalls of non-COVID-19 products continue apace, reinforcing that quality challenges are not unique to diagnostic tests and PPE.

While the focus on COVID-19-related products is rightly a priority for the FDA, the agency also continues to wrestle with emerging device technologies, including the integration between hardware and software. The regulation of software as a medical device (SaMD) remains a challenging and much discussed issue, and the FDA has been busy over the past year implementing provisions of the 21st Century Cures Act of 2016, which attempted to balance oversight and innovation..


BILL MCCONAGHA

The FDA issued a final guidance document in July detailing the regulation of multiple-function device products, which builds on related guidances issued in previous years to clarify the agency's current thinking with respect to SaMD. This guidance is timely, as firms seek more clarity on the development and management of compliant software in increasingly complex medical devices. It also calls on manufacturers to perform risk assessments to evaluate whether the non-device functions of their products affect the safety or efficacy of the device functionality.

The guidance reinforces the complexity of this area and the agency's attempts to navigate the applicable provisions in 21st Century Cures. We expect heightened scrutiny ahead, especially as the FDA resumes domestic inspections and begins to review the quality of manufacturers' decision-making in this space.

The same FDA guidance highlights concerns related to

cybersecurity vulnerabilities – another issue of growing concern among manufacturers, health care organizations and regulators, particularly in light of the increasing number of cyberattacks targeted at the health care industry. Earlier this year the agency informed health care providers and the public about emerging cybersecurity vulnerabilities in certain medical devices and health care facilities, and the associated risks for patient harm. The FDA cautioned that those risks will proliferate as devices are increasingly connected to the internet, hospital networks and other medical devices.

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This heightened regulatory interest in device software is shared by Australia's Therapeutic Goods Administration, which released a report in July called "Actual and Potential Harm Caused by Medical Software." The report catalogues risks associated with software in devices, and may be a harbinger for increased scrutiny and recalls in the US. Reports suggest there were as many as 627 software-related recalls of devices in the first half of this decade, affecting nearly 1.5 million units. Given the regulatory and functional complexities associated with powerful new software, there is good cause to believe the trend will continue.

A Complex Regulatory Landscape

In short, the regulatory landscape for medical devices is as complex as ever. Advances in technology and functionality present ever-more complicated regulatory questions for the FDA. Devices are quite literally the front line of the fight against COVID-19, and the agency has devoted incredible energy to the authorization of necessary products and the interdiction of the bad.

And now the Department of Health and Human Services, which oversees the FDA inside the executive branch, has reversed the agency's approach to reviewing laboratory developed tests (LDTs) used in the diagnosis of COVID-19 on the grounds that the FDA cannot subject LDTs to premarket review in the absence of final regulation requiring as much. This raises a series of complex questions about how – and whether – the FDA will continue to regulate LDTs, and whether Congress will intercede.

As a result, strains in this space seem inevitable. As device technology becomes more complex and consumer demands tax the global supply chain, the quality issues, recalls and incidence of fraud are certain to keep pace.

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