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PRESSURE ON MEDICAL DEVICE COMPANIES IS HIGH, AND RECALLS FREQUENT, AMID COVID-19

As medical device companies work to meet the increased demand for critical equipment and personal protection products 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.

FDA 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 more recent efforts to rid the marketplace of underperforming or illegal products.

To this end, 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, FDA 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. In addition, 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, thereby increasing the exposure risk to others.

At the same time, recalls of non-COVID products continue apace, reinforcing that quality challenges are not unique to diagnostic tests and PPE. In addition to the adulterated hand sanitizers discussed elsewhere in this update, recent recalls have implicated quality issues as varied as Infant Formula filled with water, allegedly contaminated PS Primer Water, and lidocaine patches manufactured without adequate quality controls.

While the focus on COVID-related products is rightly a priority for 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 FDA has been busy over the last year implementing provisions of the 21st Century Cures Act of 2016 that attempted to balance oversight and innovation.

On July 29, 2020, FDA issued final guidance detailing the regulation of multiple function device products, which builds on related Guidances issued in previous years to clarify FDA'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.

The guidance 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 FDA resumes domestic inspections in the near term and begins to review the quality of manufacturer's decision-making in this space.

The same guidance highlights concerns related to cybersecurity vulnerabilities – another issue of growing concern among manufacturers, healthcare organizations and regulators, particularly in light of the increasing number of cyberattacks targeted at the healthcare industry. During the first quarter of 2020, FDA informed healthcare providers and the public about emerging cybersecurity vulnerabilities in certain medical devices and healthcare facilities and the associated risks for patient harm.

The FDA cautioned that such risks will proliferate as medical devices are increasingly connected to the Internet, hospital networks, and other medical devices.

This heightened regulatory interest in device software is shared by Australia's Therapeutic Goods Administration (TGA), which released a report in July 2020 titled "Actual and Potential Harm Caused by Medical Software." The report catalogues risks associated with software in medical devices, and may be a harbinger for increased scrutiny and recalls in the United States.

Reports suggest there were as many as 627 software-related recalls of medical 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.

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. Medical devices are quite literally the front line of the fight against COVID-19, and FDA has devoted incredible energy both to the authorization of necessary products and the interdiction of the bad. The White House now seems poised to reverse FDA's approach to the regulation LDTs used in diagnosis of the disease. Strains in this space seem inevitable.

As device technology gets 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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