Promotion of Devices Subject to the FDA's COVID-19 Enforcement Policies

The Biden Administration's withdrawal of the Trump Administration's proposal to exempt 84 medical device types from the FDA's premarket notification, or 510(k), requirement, underscores the promotional framework that developers and marketers of these devices are subject to. The Trump Administration proposal included devices critical to combating the COVID-19 public health emergency, ranging from personal protective equipment and ventilators to remote patient monitoring and other types of digital health devices.

Read more about promotional considerations for these devices **here**.

SEC Chairman's Comments Signal Likely Changes to Rule 10b5-1 Trading Plans

Rule 10b5-1 trading plans have faced increased scrutiny since the onset of the COVID-19 pandemic and the corresponding public focus on stock sales by executives of public **life sciences companies**. On June 7, 2021, SEC Chairman Gary Gensler continued that scrutiny when he delivered prepared **remarks** to the *Wall Street Journal*'s CFO Network Summit concerning Rule 10b5-1 trading plans and his view that "these plans have led to real cracks in our insider trading regime." Mr. Gensler outlined four potential reforms that the SEC staff is considering to address those "cracks".

Read the full insight **here**.