Common GCP Bioresearch Monitoring Violations

The U.S. Food and Drug Administration's (FDA's) Office of Bioresearch Monitoring Operations (OBIMO) oversees domestic and foreign agency field inspections for clinical and non-clinical research. In particular, OBIMO manages the Bioresearch Monitoring (BIMO) Program which conducts onsite field inspections and data monitoring to ensure institution and industry compliance with FDA's regulations relating to Good Clinical Practices (GCPs). These inspections can occur as a result of a marketing application submission, for general surveillance during an ongoing clinical trial, or as a result of a "for cause" reason. After an inspection, FDA investigators may issue a Form 483 to communicate any onsite findings of noncompliance with FDA's regulations. BIMO also has authority to issue Warning Letters when the noncompliance FDA identifies is serious.

In the past 5 years, following are the three most common violations found in OBIMO Warning Letters:

1. **Failure to ensure that the clinical trial was conducted according to the investigational plan**. For example, in one Warning Letter, the FDA noted that a clinical investigator failed to adhere to the investigational plan because subjects took less than the required dosing of the study drug, and some subjects may have taken placebo rather than the required study drug, calling into question the validity of the study data.
2. **Failure to maintain adequate and accurate study records, including the case histories of individual subjects, the disposition of the drug, or signed informed consent forms**. For example, in one Warning Letter, the FDA found that a clinical investigator failed to complete diagnosis summary score sheets for multiple subjects, and the same clinical investigator also failed to accurately report the amount of drug dispensed versus the amount of drug taken by the subject.
3. **Failure to ensure that proper informed consent was obtained**. In several Warning Letters, the FDA determined that the investigators had failed to obtain proper informed consent from participants, including instances where exculpatory language was used waiving the participants' legal rights, other necessary elements of informed consent were missing, and the form was not specific to the study or approved by the institutional review board.

Sponsors and sites should review **FDA's BIMO Compliance Program Guidance Manuals** to better understand their responsibilities during clinical trials to ensure GCP compliance and to ensure readiness for future FDA BIMO inspections, should they occur. Anyone who has run a clinical trial will tell you that no trial is perfectly executed; deviations can and will occur, so preparedness is necessary. An effective monitoring program is critical to sponsors ultimately ensuring the integrity of their clinical trial records and data set. The Goodwin FDA Regulatory team works closely with sponsors on managing GCP issues when they arise during clinical trials.

Connect with our Goodwin FDA team to learn more.

*Madeline Fuller, a 2021 summer associate in Goodwin's Washington, D.C. office, contributed to this post.

Biden Executive Order Calls for Heightened Antitrust Scrutiny

On July 9, 2021, President Joe Biden announced a broad executive order (the "Order"). The Order is intended to boost what it characterizes as stagnant competition across the U.S. economy. The Order encourages federal antitrust agencies to "fairly and vigorously" enforce antitrust laws, encourages antitrust and other agencies to focus on perceived competition problems in key industries, and "reaffirms" the authority of the U.S. antitrust agencies to challenge previously consummated transactions. This sweeping Order is likely to launch a series of policy reevaluations and new rulemakings across a multitude of federal agencies.

Read the **client alert**.

PE Investment in Health Care Attracting Greater Federal Scrutiny

Private equity investment in health care companies has garnered increasingly critical attention from the federal government, including recent scrutiny by

Congress in March 2021, when the Oversight Subcommittee of the U.S. House of Representatives' Ways and Means Committee held a hearing on "Examining Private Equity's Expanded Role in the U.S. Health Care System."

The tenor of the hearing is encapsulated in the opening remarks of the Oversight Subcommittee's Chairman, U.S. Representative Bill Pascrell Jr. (D-N.J.), who kicked off the discussion by cautioning that: "It's past time for a bright light to be shined on how private equity ownership and our health care system affects patient safety, cost, and jobs." Noting that 2020 saw $66 billion in private equity investment across the health care industry — a 21% increase from 2019 — Chairman Pascrell expressed concern that "private equity's main focus — profit — is often at odds with what is best for patient care."

Read the **full *New York Law Journal* article**.

Biden Executive Order Targets Competition in Healthcare, Life Sciences to Spur Economic Activity

On July 9, 2021, President Joe Biden issued an **Executive Order** (the "Order") designed to promote competition in the American economy. The Order describes the administration's concerns with competition in several markets, including healthcare, noting that industry consolidation has exacerbated racial, income and wealth inequality and emphasizing that robust competition is critical to the United States economy.

In this Order, to combat these concerns, the Biden administration affirms (i) its policy to support legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices and by imposing inflation caps; and (ii) its policy to support the enactment of a public health insurance option.

Read the **client alert**.

Navigating the New Normal: Biomanufacturing Goes Local

 The pandemic has spared no industry. The life sciences industry knows this well and perhaps learned this lesson the hardest way during the pandemic when overseas supply shipments were delayed or, worse, when overseas manufacturing facilities were shut down because of government-mandated quarantines. Producing novel biologics is, unfortunately, not so easy to pick up and relocate, especially during a pandemic and even moreso when there are not enough domestic producers to begin with. As the life sciences industry continues to rapidly grow and mature in the U.S., life sciences clusters are growing and expanding into the next phase: biomanufacturing onsite and building their own self-sustaining supply operations. Learn more about the expansion of the domestic supply chain here.

Read the **full insight**.