Alere Pays $198.75 Million to Settle False Claims for Allegedly Billing Medicare for Defective POC Devices, Not Charging Copays, and Sending Supplies to Deceased Patients

Alere Inc. and Alere San Diego Inc. (collectively "Alere") have come under fire recently by the U.S. Department of Justice ("DOJ") and other government agencies, agreeing to settle several rounds of accusations of False Claims Act violations for a total of $198.75 million.

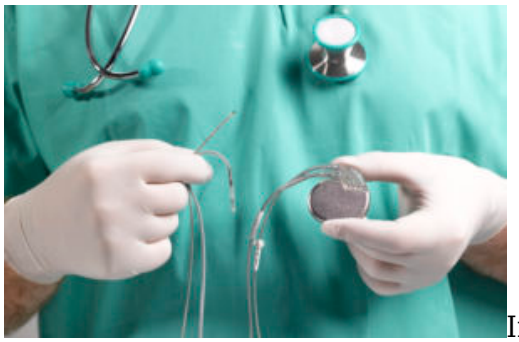
The first series of settlements was **announced** by DOJ on July 8, 2021 and cost the company approximately $38.75 million in fines and penalties. Here, the medical device manufacturer was alleged to have billed Medicare for rapid point-of-care testing devices that Alere knew were defective. More specifically, the government alleged that the INRatio blood coagulation monitors (manufactured by Alere) were defective. The monitors were used by Medicare beneficiaries taking anticoagulant drugs to monitor their blood coagulation. Anticoagulants drugs can cause major bleeding when used in access or blood clots and strokes can develop when not enough medication is taken. DOJ alleged that Alere concealed the fact that the device was producing inaccurate results for some patients, resulting in several deaths and hundreds of injured beneficiaries. This practice was ongoing for a total of eight years, according to DOJ.

One month after this first massive settlement was announced, the DOJ **announced** an even more sizable settlement with Alere Inc.'s subsidiary, Arriva Medical ("Arriva"), a diabetes testing equipment supplier, totaling an additional $160 million to settle false claims related to an alleged kickback scheme. The DOJ purported that, from April 2010 through December 2016 – immediately prior to Abbott's $5.3 billion acquisition of Alere in 2017 – Arriva (1) regularly waived and failed to collect Medicare beneficiaries' cost-sharing amounts (i.e. copays); (2) sent glucose meters at no cost to patients; and (3) sent diabetic testing equipment to deceased patients.

Medical device makers, durable medical equipment suppliers, and Medicare providers of all sorts should take heed of these recent settlements and implement regular third party compliance and billing audits as part of their Compliance Program to help ensure that practices are aligned with government expectations and rules. In addition, companies acquiring, merging with, or investing in healthcare entities should incorporate complete third party billing and compliance testing as part of their due diligence in connection with these types of transactions to identify billing-related risks.

If you have any questions, please contact Anne Brendel (**abrendel@goodwinlaw.com**; 415-733-6047) or Matt Wetzel (**mwetzel@goodwinlaw.com**; 202-346-4208).

Patient Stakeholder Group Zeroes in on Medical Device Industry

 In recent months, the Kaiser Health Network (part of the Kaiser Family Foundation) has issued three reports scrutinizing the orthopedic industry and its practices. Each report articulates the stakeholder group's concerns over relationships among orthopedic and spinal surgeons, orthopedic implant manufacturers, and their sales representatives. Medical device manufacturers, especially those in the orthopedic space, should pay careful attention.

- **The first report** (June 2021) dives deeply into payments made by medical device makers to orthopedic surgeons who use their products. Kaiser highlights government allegations against orthopedic medical device makers (focusing specifically on the recent **SpineFrontier matter**) that they pay "sham consulting fees" to spinal surgeons for "doing little or not work." Kaiser identifies what it considers to be troublesome payments from medical device makers to surgeons that implant their products, including royalty payments (for "helping to design implants"), speakers' fees ("for promoting devices at medical meetings"), to stock ownership provided in exchange for consulting. Kaiser notes that, from 2013 through 2019, the orthopedic industry has paid $3.1 billion to its surgeon consultants, highlighting the potential to "corrupt medical judgment and tempt surgeons to perform unnecessary and wasteful operations." The patient stakeholder group also spotlights what it considers to be a "startling array of schemes to influence surgeons," including compensation for joining a medical society created by a medical device company; purchasing billboard space to advertise medical practitioners; providing employment to surgeon's relatives, and entertainment/sporting activities. The patient stakeholder group also emphasizes that "more than 600,000 American doctors lap up industry largesse . . . [mostly] through small payments that cover the cost of food, drinks, and travel to industry-sponsored events."

- **A second report** (August 2021) highlights the relationships between orthopedic makers and their sales reps, who are often called upon to provide technical support to surgeons in the operating room during surgeries. Device makers assert that having sales representatives must be present for certain procedures to ensure the proper functioning of highly complicated surgical equipment and to make sure that the right scope of surgical tools and equipment are available. Critics, however, argue that the practice demonstrates the coziness between sales reps and physicians. The Kaiser report states that it is like "the relationship of a caddy and an avid golfer" and that "[d]uties can include lugging 20-pound sets of surgical hardware to the operating room, assuring it is sterile and knowing its specifications," even though – according to Kaiser – reps are not required to be trained medically. Critics further assert that companies are spending excessively for top sales talent, and the amount of money creates bad incentives,

including failures to track injuries and pushing for unneeded surgeries. The result, according to Kaiser, is an increase in patient injuries and harm, which the stakeholder group asserts often go unreported.

- **A third report** (August 2021) places a spotlight on the issue of orthopedic surgeons taking ownership interests in private medical device companies, often referred to as PODs, including highly lucrative payments for selling and using products and as a result of larger medtech companies purchasing privately held medical device makers. Kaiser highlights the potential for incentivizing unnecessary surgeries and the negative consequences on patients. CMS has, in fact, **recently proposed updates to its Open Payments (Sunshine Act) program** to clarify requirements for physician-owned distributors to help ensure all of these payments are appropriately captured, reported, and publicly disclosed.

Should medical device makers pay attention to the Kaiser reports? Yes, especially makers of orthopedic devices. Increased interest from key patient stakeholder groups like Kaiser can only mean that others are also watching. We have not seen any let-up in the continued enforcement of the federal fraud and abuse laws against medical device companies. And as the government keeps the heat on the orthopedic industry, **companies should consider undertaking an independent, third-party compliance assessment** that addresses the following:

- Policies and practices on engaging health care providers to serve as consultants, including selection criteria, evaluation of payments, controls to limit influence, and documentation of services provided, focusing on royalties, speaker fees (see **OIG's November 2020 Special Fraud Alert on Speaker Programs**), and payments for technical training, among others.

- Policies and practices on physician ownership, including whether there are appropriate controls and measures for assessing when it is appropriate to provide ownership interests to physicians, especially given CMS's recent ramp-up of interest in physician-owned distributorships.

- Policies and practices relating to sales representatives in the operating room to support procedures, including identifying the extent to which videoconferencing and other virtual technologies might be used instead of permitting a rep's in-person presence in the operating room.

- Policies and practices on disclosure of payments and transfers of value made to physicians and other healthcare practitioners (as required under the Sunshine Act) and conflicts of interest, as these concerns are central to the criticisms lobbed by Kaiser and by the government in its enforcement actions.

A periodic, independent review of compliance practices helps ensure better alignment not only with federal healthcare fraud and abuse laws but also with compliance best practices and ethical principles that prioritize and protect patients. If you have any questions, please contact Matt Wetzel (**mwetzel@goodwinlaw.com**) or (202-346-4208).

PhRMA Issues Updates to Longstanding Code, Addresses OIG's Speaker Program Guidance

PhRMA, the pharmaceutical manufacturer trade association, **announced on Fri. August 6** that it has revised its **longstanding Code on Interactions with Health Care Professionals**. The revisions, which relate to the Code's treatment of speaker programs, track concerns in a **Special Fraud Alert** released late last year by the US Department of Health and Human Services Office of Inspector General. This alert criticized the drug and medical device industry practice of engaging healthcare providers to deliver educational content to potential customers or users of products through so-called "speaker programs." The OIG found in its report that speakers were selected based on past or anticipated business; that attendees of these programs were offered remuneration in the form of lavish meals and alcohol; that programs were often held in high-end locations, often without an agenda, and often without any educational content delivered at all. The OIG also noted its findings that attendees of speaker programs regularly attend the same program more than once, calling into question their educational value. The alert expressly notes OIG's "skepticism" about such programs.

PhRMA appears to be the first of the major medical products trade associations to update its code of ethics based on the OIG's November 2020 alert. The PhRMA Code revisions from August 6 appear to address the criticisms raised by OIG. PhRMA expands its section 7 discussion of Speaker Programs, emphasizing the importance of speaker programs as a real and legitimate avenue of educating customers and product users about the benefits, risks, and science of particular products. Among the revisions:

- The PhRMA Code reiterates that incidental meals of modest value may still be offered to attendees but that they should be subordinate in focus to the educational presentation. The revisions also make it clear that companies should not pay for or provide alcohol at a speaker program, one of the OIG's chief complaints in the November 2020 alert.
- The revisions make clear that the purpose of any speaker program must be to present substantive educational information designed to help address a bona fide educational need among attendees, and that only those with a bona fide educational need should be invited. The revisions also highlight that repeat attendance at a program on the same or substantially same topic is generally not appropriate unless there is a bona fide educational need for the additional information.
- PhRMA emphasizes that the venue should be conducive to informational communication – no extravagant venues, luxury resorts, high-end restaurants, or entertainment/sporting venues.
- Further, the PhRMA Code also spotlights the fact that speakers should be engaged following the guidelines for engaging consultants as described in the PhRMA Code – including selection based on expertise and professional qualifications rather than past or anticipated business.

Revisions to the new PhRMA Code become effective January 1, 2022. This gives companies just a few months to evaluate their compliance policies and to update messaging to their employees regarding the appropriate set-up and operation of speaker programs, if any revisions to current practices are required.

If you have questions about this update, please contact Matt Wetzel (**mwetzel@goodwinlaw.com**, (202) 346-4208).

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**.

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**.

Drug Development Scorecard — A Guide for Companies Navigating the FDA Drug and Biologic Development and Approval Process

Developing a new drug or biologic is a complex process. Based on our extensive experience advising early-stage and clinical-stage companies, the Goodwin FDA

team created this "**scorecard**" for companies to use as a guide as they navigate the FDA drug development and approval process. The drug development scorecard (or checklist) can help companies keep track of progress, identify opportunities, and achieve milestones that are appropriate for each stage of development.

If you have product development or approval strategy questions, we encourage you to contact the Goodwin FDA team.

FDA Answers New Questions on Foreign Trial Sites Operating Under INDs

On May 19, 2021, the U.S. Food and Drug Administration (FDA) released an **updated guidance** in draft form on how to complete the Statement of Investigator form (Form FDA 1572). The guidance addresses frequently asked questions from sponsors, clinical investigators, and institutional review boards (IRBs), and it provides new information on waivers of the Form FDA 1572 signature requirement, which is particularly relevant for sponsors of clinical trials that include sites located outside the U.S.

Form 1572 is an agreement signed by an investigator to provide certain information to the sponsor and comply with FDA regulations on conducting a clinical investigation of an investigational drug or biologic, and under 21 CFR Part 312, an investigator must sign this agreement before participating in a trial. FDA's **previous guidance** on the Form 1572 requirements and process, issued in 2010, touches briefly on the responsibilities of investigators conducting foreign studies under an investigational new drug application (IND) in the U.S., but it does not go into detail on how sponsors should proceed when an ex-U.S. investigator cannot or will not sign the 1572 (e.g., because the commitments for investigators on the Form 1572 extend beyond or conflict with what local law requires).

Under the updated guidance, FDA provides detailed steps for sponsors to request a waiver of the Form 1572 signature requirement for foreign investigators. A Form 1572 waiver allows a trial at a foreign site to take place under an IND even when the investigator cannot or will not sign the Form

1572, as noted above. When requesting a waiver, the sponsor should propose an alternative course of action to adequately satisfy the purpose of a signed Form 1572, and the sponsor must request and receive a 1572 waiver for an investigator before the study is initiated at the investigator's site. Importantly, the guidance provides examples of sponsor and investigator commitment statements that would satisfy FDA's guidelines for granting a waiver, and FDA recommends using these templates to enable FDA's efficient review of a waiver request.

Overall, the guidance provides greater clarity on when a Form 1572 waiver would be needed and how a sponsor can obtain one. Sponsors planning to conduct a clinical study at a foreign site under an IND should review the updated guidance and, if a waiver is needed, factor in time for submission and FDA review of a waiver request before initiating the trial at a foreign site. Additionally, sponsors should ensure that clinical trial agreements with foreign sites contemplate Form 1572 completion and signatures and/or waivers when necessary.