New OIG Advisory Opinion Impacts Pharmaceutical & Medical Device Company Funding of Continuing Education Programs

OIG Advisory Opinion 22-14 (June 29, 2022) could have significant implications for how life sciences companies (pharmaceutical, medical device, and diagnostics test makers) contribute towards continuing education ("**CE**") programs for healthcare providers ("**HCPs**"). Specifically, in AO 22-14, the U.S. Department of Health & Human Services Office of Inspector General ("**OIG**") rejects a Requestor's proposal to permit pharmaceutical and medical device industry sponsorship of a CE program for HCPs, noting that it could generate prohibited remuneration under the Federal Anti-Kickback Statute.

Read the full Washington legal Foundation's Legal pulse blog post **here**.

Whistleblower Lawyers Use False Claims Act to Target Private Equity Firms Invested In Healthcare and Life Sciences

Recent developments demonstrate that the health care industry – including life sciences companies – continues to be subject to heightened regulatory scrutiny and enforcement risk. This alert addresses the U.S. Department of Justice ("DOJ") use of the False Claims Act ("FCA") to pursue private equity investors and their portfolio companies, including life sciences companies. While DOJ has been actively investigating private equity portfolio companies, the driver behind the majority of DOJ's investigations are whistleblower plaintiff lawyers who file *qui tam* suits alleging FCA violations. These lawyers have found a receptive audience in both legislative and executive branches of the federal government and are bringing pressure on DOJ to ramp up its focus on the private equity

industry, a perceived deep-pocket in FCA cases. Our lawyers **Kirk Ogrosky**, **Anne Railton**, **John LeClaire** and **Chris Wilson** examine the issue in this **client alert**.

Common Bioresearch Monitoring Violations: Updates from FY 2021 to Now

 The Bioresearch Monitoring Program (BIMO), run by the U.S. Food and Drug Administration (FDA), oversees the conduct of on-site inspections and data audits of FDA-regulated research in support of new product development and marketing approvals. As a follow up to our **July 2021 post**, we highlight here the most common violations FDA's BIMO identified in Fiscal Year (FY) 2021 along with those we have seen so far in FY 2022. Our review focuses on BIMO's clinical investigator, sponsor, and contract research organization (CRO) inspection outcomes across 516 inspections conducted in FY 2021, as these comprised nearly 85 percent of all BIMO inspections.

Amongst these, 81 percent did not result in any findings of noncompliance. Eighteen percent resulted in findings of noncompliance but without recommending regulatory action, and about one percent resulted in findings of noncompliance recommending official regulatory action. In FY 2021, the most common violations leading FDA to issue a Form FDA 483, FDA's official form for documenting noncompliant inspection findings, included:

- **Failure to submit an IND application.** For example, FDA issued several Warning Letters for investigations of dietary supplements or foods determined by the FDA to be drugs. FDA found that the study designs demonstrated the investigational products were intended to cure, mitigate, and/or treat a disease or condition, triggering application of FDA's drug authorities and requiring an Investigational New Drug (IND) application to be in place before conducting the research.

- **Failure to follow the investigational plan and implement corrective or preventive action plans.** For example, in one **Warning Letter** resulting from a BIMO inspection, the FDA noted that the investigator failed to exclude subjects according to the study's exclusion criteria and did not identify any procedures in place to prevent future violations.

- **Inadequate or inaccurate recordkeeping (including case histories, study records, and drug disposition records).** For example, in one recent **Warning Letter** following a BIMO

> inspection, the FDA noted that a study site failed to retain necessary documents for 2 years following marketing approval when it could not locate informed consent forms and case report forms, amongst others, from a study for which a Biologics License Application was pending.

Of note, these continue to be the most frequently cited violations in BIMO Warning Letters issued to date in 2022. To avoid these missteps and better understand the scope of their respective responsibilities before, during, and after a clinical trial, sponsors, CROs and investigators should review **FDA's BIMO Compliance Program Guidance Manuals** and ensure adoption of standard operating procedures (SOPs) that provide an infrastructure for regulatory compliance. Sponsors and investigators should also ensure that they understand when an IND application is required, and review the requirements for appropriate recordkeeping during and after a clinical trial. Finally, sponsors and CROs should have mechanisms in place to both promote protocol adherence and promptly respond to any deviations when they inevitably occur. Sponsors receiving BIMO Form FDA 483s should respond with a detailed explanation of their root cause findings, corrective actions, and their plan to prevent similar missteps in the future. The Goodwin FDA team works closely with sponsors to apply FDA's Good Clinical Practice requirements and to resolve BIMO inspection findings when they occur.

Connect with our Goodwin FDA team to learn more.

*Maura Friedlander, a 2022 summer associate in Goodwin's Washington, D.C. office, contributed to this post.

Potential AI/ML Learnings to Come from FDA Public Advisory Committee Meeting on Skin Lesion Analyzer Technology in Late July

On July 28, 2022, the U.S. Food and Drug Administration (FDA) will hold a public advisory committee meeting to discuss skin lesion analyzer (SLA) technology and its application to detecting skin cancers in various patient care settings. This meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee will focus on algorithm-based SLA devices for adjunctive detection of skin lesions, including skin cancers, and stands to provide industry another layer of thinking on FDA's perspective on artificial intelligence and machine learning (AI/ML) device technologies.

In announcing this meeting, FDA explained that in recent years it has observed an increased interest in SLA devices employing AI/ML. The agency is seeking expert input from the panel on approaches

to evaluate the performance of SLA devices, which have a range of technologies and indications.

The committee will discuss and provide recommendations to FDA on: (1) the diagnosing standard, or ground truth, that should be used as a comparison for the performance of diagnostic devices, e.g., histology, consensus opinion of a panel of dermatologists, opinion of a single dermatologist, or other means; (2) acceptable sensitivity and specificity thresholds based on the target diagnosis (melanoma, basal cell carcinoma, squamous cell carcinoma) or intended user (dermatologist, primary care physician, lay user); (3) patient characteristics, including lower or higher incidence populations, that should be tested before marketing; and (4) the balance of increased access with risk mitigation measures that are appropriate when the devices are used by lay people, by populations with very high or very low incidence of melanoma, by populations with low incidence, but high mortality associated with melanoma, or by the target diagnosis/lesion type.

Additionally, on July 29, 2022, the committee will discuss the possible reclassification of two class III, PMA approved computer-aided melanoma detection devices, MelaFind (P090012) and Nevisense (P150046), both of which are intended for use on cutaneous lesions suspicious for melanoma when a dermatologist chooses to obtain additional information when considering biopsy. According to the FDA announcement, "The committee will discuss if there is sufficient information to reclassify computer-aided devices for adjunctive diagnostic information of lesions suspicious for melanoma from class III to class II, and what special controls may be appropriate to provide reasonable assurance of safety and effectiveness" if they are reclassified.

This meeting, and any actions the FDA takes as a result, could offer industry further insight into the FDA's approach to regulating AI/ML diagnostic and screening products more broadly.

The meeting will be held virtually on July 28, 2022, from 9 am to 5:45 pm ET and July 29, 2022, 9 am to 4 pm ET. Comments received on or before July 11, 2022 will be provided to the committee and the public docket will remain open for comment for FDA's consideration until August 29, 2022.

For more information see the **Meeting Notice on the Federal Register**.

Canadian Patent Examination Will Soon Be More Expensive, Less Flexible and Require Additional Care in Prosecution to Avoid Loss of Rights

Canadian Patent Examination

Significant fee increases will be effective at the Canadian Intellectual Property Office (“CIPO”) on October 3, 2022 related to excess claims (claims over 20) and the number of examination reports it issues during prosecution. These changes may negatively impact the breadth of patent protection an applicant could pursue in Canada and will likely also require additional care in strategic filing choices during patent examination. Prior to October 3, 2022, applicants should consider requesting examination for pending applications in order to minimize the impact of these fees (the fee increase will not apply to patent applications for which a request for examination is filed prior to October 3, 2022).

Read the client alert **here**.