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## **Department of Justice**

U.S. Attorney's Office

District of Massachusetts

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## BioReference Laboratories and Parent Company Agree to Pay \$9.85 Million to Resolve False Claims Act Allegations of Illegal Remuneration to Referring Physicians

BOSTON – BioReference Health, LLC, formerly known as BioReference Laboratories, Inc., (BioReference) and OPKO Health, Inc. (OPKO) have agreed to pay \$9.85 million to resolve alleged violations of the False Claims Act. The government alleges that BioReference rented office space from physicians and then paid those physician-landlords above-market rent so that the physicians would send their laboratory business to BioReference. BioReference, a subsidiary of OPKO, is headquartered in New Jersey and is one of the largest clinical laboratories in the United States.

Between January 2013 and March 2021, BioReference made lease payments to physicians and physician groups for the rental of office space for amounts that exceeded fair market value, in violation of the Physician Self-Referral Law and the Anti-Kickback Statute. The Physician Self-Referral Law, commonly known as the Stark Law, prohibits a health care provider from billing for certain services referred by physicians with whom the provider has a financial relationship, unless that relationship satisfies one of the law's statutory or regulatory exceptions. The Anti-Kickback Statute prohibits offering or paying remuneration with the intent to induce the referral of items or services covered by Medicare, Medicaid, and other federally funded programs. Both the Stark Law and the Anti-Kickback Statute are intended to ensure that physicians' medical judgments are not compromised by improper financial inducements.

As part of today's settlement, BioReference admitted that it rented the office space from the specified physician practices for Patient Service Centers (PSCs) where patients could have their blood samples taken. In calculating payments under certain PSC lease arrangements, BioReference inaccurately measured the amount of space it would use exclusively and included a disproportionate share of common spaces. BioReference analyzed referrals from nearby health care providers—including physician-landlords—when deciding whether to open, maintain, or close PSCs. Following OPKO's acquisition of BioReference, the companies conducted multiple internal audits that showed that the payments to the specified physician-lessors exceeded fair market value. BioReference did not report or return any overpayments to federal health care programs.

"Medical decisions by doctors should be based on what is best for each patient, not a doctor's personal financial interest," said United States Attorney Rachael S. Rollins. "When companies violate the federal

health care laws that are meant to protect patients, health care costs for hard working people increase. We will continue to find fraud and use the False Claims Act to make companies that break the law pay back the taxpayers they defrauded as well as pay a financial price for their misconduct."

"The integrity of federal health care programs depends on providers making decisions based on the interests of their patients," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "The Department of Justice and its agency partners are committed to enforcing laws prohibiting illegal financial arrangements that may distort health care decision-making and drive up costs to federal health care programs and patients."

In connection with the False Claims Act settlement, BioReference and OPKO have also entered into a five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General, which provides for periodic reviews of BioReference's processes, policies, and transactions for compliance with the Anti-Kickback Statute and the Stark Law by an Independent Review Organization.

"This settlement is a warning to laboratories that think they can boost their profits by entering into improper financial arrangements with referring physicians," said Special Agent in Charge Phillip M. Coyne of the U.S. Department of Health and Human Services, Office of Inspector General. "Working with our law enforcement partners, we will continue to crack down on such deals, which work to undermine impartial medical judgement, drive up health care costs, and corrode the public's trust in the health care system."

"Laboratories that scheme to enrich their businesses through health care fraud—such as by paying kickbacks—drive up health care costs for everyone," said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division. "This settlement shows how seriously the FBI takes its responsibility to weed them out, and we'd also like to thank the whistleblower in this case for helping us ensure these entities are held accountable."

"When health care companies pay unlawful remuneration to physicians and submit false claims for improper referrals, they undermine the integrity of TRICARE and place an unnecessary financial burden on the program," stated Special Agent in Charge Patrick J. Hegarty of the Defense Criminal Investigative Service, the law enforcement arm of the Department of Defense Office of Inspector General. "The settlement agreement announced today demonstrates our ongoing commitment to work with our law enforcement partners to investigate healthcare fraud and protect TRICARE, the healthcare system for military members and their dependents."

The False Claims Act allegations being resolved were originally brought in a lawsuit filed by a whistleblower under the qui tam provisions of the False Claims Act. Under those provisions, a private party can file an action on behalf of the government and share in any recovery. In connection with today's settlement, the whistleblower will receive 17 percent of the recovery.

Under the settlement, the defendants will also pay approximately \$145,000 to the Commonwealth of Massachusetts and the State of Connecticut to resolve alleged violations of their respective state False Claims Acts.

U.S. Attorney Rollins, HHS-OIG SAC Coyne, FBI SAC Bonavolonta and DCIS SAC Hegarty made the announcement today. Assistant U.S. Attorneys Alexandra Brazier and Charles B. Weinograd of Rollins's Affirmative Civil Enforcement Unit, and Trial Attorney Douglas Rosenthal of the Justice Department's Civil Division, Commercial Litigation Branch, handled the matter.

## Download BioReference Settlement Agreement.pdf

Topic(s):

False Claims Act

Component(s):

<u>USAO - Massachusetts</u>

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