DOJ probes device maker whose test resulted in lucrative diagnoses for UnitedHealth and other insurers

Semler discloses fraud investigation related to its peripheral artery disease test

The QuantaFlo device plugged into a laptop.

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The Department of Justice is investigating Semler Scientific for possible violations of a federal anti-fraud law related to its marketing of a product known as QuantaFlo, a test used in the diagnosis of peripheral artery disease by UnitedHealth Group and other large insurers.

In a recent filing with the Securities and Exchange Commission, Semler disclosed that the government is investigating the use of QuantaFlo related to claims made for reimbursement from government health programs, which in some cases pay insurers more money to cover patients diagnosed with peripheral artery disease.

The SEC filing states that on Feb. 11, Semler began — but then cut off — settlement discussions with the Department of Justice related to possible violations of the False Claims Act, an anti-fraud law designed to prevent companies from collecting unwarranted payments from the federal government. The company indicated that the investigation began in 2017 and picked up in intensity in late 2024 and early 2025.

News of the federal probe follows a STAT investigation that found UnitedHealth Group, the nation's largest Medicare Advantage insurer, dramatically boosted reimbursements from Medicare by using QuantaFlo to screen patients for peripheral artery disease. The investigation found that many of the diagnoses were not medically useful, either because they were false positives or because they flagged early-stage disease, which isn't typically treated, according to nine clinicians.

Semler Scientific, based in California, did not immediately respond to a request for comment from STAT. In the SEC filing, company officials wrote that they intend to "vigorously defend ourselves" against any charges filed by the government.

UnitedHealth Group also did not immediately respond to a request for comment. In a statement provided in response to STAT's findings last year, UnitedHealth Group wrote: "Screening patients with an increased risk for PAD aligns with guidance provided by the American Heart Association and the American College of Cardiology, and helps to identify and treat an under-diagnosed condition that, if left unmonitored and untreated, can lead to serious health consequences."

Doctors with expertise in managing artery disease told STAT during its investigation that they would not diagnose a patient with peripheral artery disease based on a positive result from QuantaFlo alone, and would seek to confirm the finding with a gold standard exam known as the ankle brachial test.

QuantaFlo calculates artery blood volume by measuring reflected infrared light through sensors placed on a patient's fingers and toes. It was cleared by the Food and Drug Administration in 2015 through a pathway that requires limited clinical testing. It is meant to serve as a tool to aid doctors in diagnosing PAD, not to be used as a standalone diagnostic device.

Semler asserts that no such confirmatory testing is necessary.

"QuantaFlo PAD is a stand-alone test that supports clinicians in the early diagnosis of PAD and does NOT require confirmation by cuff-based ABI," the company says on its website.

Some vascular clinics use the test, but Semler's biggest customers are private insurers — including UnitedHealth Group, which used QuantaFlo to screen patients for artery disease in their homes and in clinics. Each diagnosis of the disease is worth about $3,000 a year in reimbursement from Medicare. UnitedHealth Group dramatically scaled up use of QuantaFlo in recent years through its HouseCalls program, in which it sends clinicians to the homes of insured patients to conduct medical examinations and test patients for various chronic illnesses.

Signify Health, a company owned by CVS Health that conducts home visits for Medicare Advantage insurers, also used the test on behalf of several large clients.

It was in 2017, the year the SEC filing suggests the DOJ investigation began, that UnitedHealth Group began to dramatically expand use of QuantaFlo in its HouseCalls program.

From 2018 to 2021, UnitedHealth tallied more than 1.3 million unspecified artery disease diagnoses, according to an analysis conducted for STAT by the Lown Institute, a nonpartisan health research organization. Based on the roughly $3,000 value of each diagnosis in

Medicare reimbursement, UnitedHealth took in approximately $4 billion in taxpayer money from both valid and questionable PAD diagnoses during that four-year stretch.

UnitedHealth's own data, published in late 2022, showed the company's clinicians diagnosed Medicare Advantage patients with peripheral artery disease at almost four times the rate of patients in traditional, government-run Medicare, which does not provide the same financial incentives.

In its statement last year, UnitedHealth said, "QuantaFlo is one FDA cleared tool providers may use, based on their independent clinical judgment, to assist in diagnosing patients with an increased risk for PAD and help ensure they receive appropriate follow-up care."

But many Medicare policy experts, including former leaders of the program, have argued there is no direct evidence that the increased rate of diagnosis of peripheral artery disease has led to better care — even as it caused costs to skyrocket. "[Medicare's] risk adjustment system has allowed plans to in effect set their own premium by incessantly creating, hunting for, and submitting more diagnosis codes to CMS," stated a March 2023 letter signed by 19 former Medicare officials, physicians, and policy experts.

The flood of codes for the illness and other chronic conditions, such as kidney disease and substance use disorder, dramatically boosted reimbursements to Medicare Advantage insurers, resulting in excessive payments expected to cost taxpayers $50 billion this year alone, according to the Medicare Payment Advisory Commission.