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Surge In US Enforcement Actions Shows Focus On Diagnostics

by [Elizabeth Orr](#)

An apparent spike in health care enforcement actions by the US Department of Justice has led to hundreds of millions of dollars in penalties and multiple jail sentences throughout the sector. The DOJ has announced at least 20 device-related cases since mid-September.

Diagnostic firm Genomics Health, a subsidiary of [Exact Sciences Corp.](#), agreed to pay \$32.5m to resolve allegations it had filed Medicare claims for some cancer tests. A North Carolina lab owner was sentenced to almost 17 years in prison for billing Medicaid for unnecessary drug tests for Medicaid beneficiaries. And at least 10 practitioners are facing jail time or massive fines for violations of the False Claims Act.

That's just a sliver of the health care fraud cases announced by the US Department of Justice over the last month that involved devices or diagnostics.

The US government's law enforcement arm has issued press releases on at least 20 medtech-related health care fraud cases since the middle of September, running far ahead of the typical rate. In total, the schemes billed the government more than \$1.3bn in false Medicare and Medicaid claims.

By way of comparison, the government collected a total of \$5.6bn in False Claims Act settlements for all of 2021. However, health care fraud has long been an area of focus for the Department of Justice. The agency's [health care fraud unit](#), which is part of DOJ's fraud section, employs more than 80 prosecutors and has strike force teams in regions including Los Angeles, Florida, Texas, the Gulf Coast, and New England. (Also see "[2021 False Claim Judgements Top \\$5.6Bn; Largest Net In Seven Years](#)" - Medtech Insight, 2 Feb, 2022.)

Attorney Jonathan Phillips, who is co-chair of the False Claims Act practice at Gibson Dunn, said that his firm has seen a particular increased focus on actions against diagnostic testing firms.

He believes that like the FDA's recent proposed rule on the regulation of lab-developed tests, the enforcement trend reflects concerns about the accuracy, safety and increasing complexity of diagnostics, as well as their growing role in determining how – and whether – patients are treated. (Also see "[LDT Rule Will Have Massive Impact, Analysts Say; Fundamental Questions Remain](#)" - Medtech Insight, 5 Oct, 2023.)

“Additionally, innovations in diagnostic testing often outpace federal health programs and other payors, sometimes creating a gray area for how they should be billed or described to such payors in obtaining reimbursement,” he told *Medtech Insight*. “If a company adopts billing practices in this scenario that get it wrong—or even exploit the ambiguity—and the government believes there has not been adequate transparency, there are risks of health care fraud enforcement actions.”

For example, Gibson Dunn has seen actions against companies based on alleged miscoding or mistreatment of copays, which may result from ambiguity in the space.

Doctors, Lab Owners Face Punishment

Known DOJ enforcement actions related to the device sector are listed below.

14 September: [Terrance Ballard of Irving, TX](#), pleaded guilty to his role in submitting more than \$7m in false claims for COVID-19 testing. Ballard and three co-conspirators stole patient information from labs where he worked as a tech, then filed Medicare claims that falsely said the group had provided COVID-19 tests to those patients. He faces up to seven years in prison.

[Terry Wilks Jr. of Greenwell Springs, LA](#), was sentenced to 36 months in prison after a conviction for conspiracy to pay and receive health care kickbacks. Wilks was the CEO and owner of Acadian Diagnostic Laboratories, LLC, which paid kickbacks to health care providers in exchange for referrals. One of the providers who worked with Acadian Diagnostic had previously been excluded from the Medicare program.

[Justin LaMonda of Moberly, MO](#), was sentenced to 22 months in prison and ordered to repay almost \$540,000 in fraudulent Medicare reimbursement. Former physician LaMonda had his Medicare privileges revoked for conduct violations but continued to submit claims and orders for durable medical equipment (DME) under his father's provider ID.

15 September: [Ronald Coburn of Lexington, KY](#), plead guilty to health care fraud and tax evasion. As owner-operator of LabTox LLC, he billed Medicare and Kentucky Medicaid for urine drug testing that was not medically necessary. LabTox collected \$1.9m in false payments between June 2019 and March 2021. Additionally, Coburn did not pay income taxes between 2017 and 2021, for which he is facing additional IRS penalties.

18 September: Billing consultant [*Franceene McKinney of Cincinnati*](#) agreed to pay \$30,000 in restitution and was excluded from federal health care programs for three years. She instructed providers to falsely bill Medicare under a code for surgical implantation of neurostimulator electrodes, even though the devices were being used for much simpler electro-acupuncture procedures.

Cardiologist [*Klaus Peter Rentrop*](#) and his medical practice, Gramercy Cardiac Diagnostic Services PC, both of New York City, agreed to pay \$6.5m in restitution to settle a civil fraud lawsuit. Rentrop paid kickbacks disguised as inflated rental payments to other cardiologists in exchange for referrals for diagnostic tests and procedures to be performed by Gramercy Cardiac. In addition to the financial settlement, Rentrop agreed to sell the practice and is blocked from billing federal health programs.

21 September: [*Three Missouri physicians and their pain management practices*](#) agreed to pay more than \$650,000 to resolve allegations they accepted kickbacks in exchange for referring patients for laboratory testing. The physicians are Gregory Stynowick of Pain Management Medical Center LLC and Chad Shelton and Michael Boedefeld of Pro Pain LLC. Purported management service organizations paid them thousands of dollars in exchange for referring patients to specific clinical labs.

[*Elizabeth Hernandez of Homestead, FL*](#), was convicted on multiple fraud charges for her role in a scheme that submitted more than \$200m in medically unnecessary Medicare claims for expensive genetic testing and orthotic braces. The nurse practitioner signed off on orders for the tests and equipment, falsely claiming to have treated patients she had never even spoken with. She collected about \$1.6m for her role. Hernandez is facing decades in prison and will be sentenced on 14 December.

26 September: The US government won \$370m in judgments against [*Kentucky businessman Rajen Shah*](#) and his companies United Diagnostics Lab, Tomoka Medical Lab, Tennessee Valley Regional Laboratory, Luminus Diagnostics, and Golden Rule Management for violations of the False Claims Act. Shah reportedly caused his laboratories to bill Medicare for expensive molecular tests that were not ordered by a licensed health care provider.

[*Charlotte, NC, physician Sudipta Mazumder*](#) was convicted on six counts of making false statements related to health care matters. In her role as a staff doctor for a telemedicine company, Mazumder signed fraudulent orders for medically unnecessary durable medical equipment for patients insured by the Medicare and TRICARE programs whom she had not examined or treated. She faces up to \$3m in penalties and 30 years in prison.

Former laboratory owner [*Donald Booker of Charlotte, NC*](#), was sentenced to 200 months in prison, or about 16.5 years. Booker and his cohorts got vulnerable people to submit urine samples in

exchange for housing and other services, then billed Medicaid for medically unnecessary drug tests. A jury convicted him in January on charges of conspiracy to commit health care fraud, multiple violations of the anti-kickback statute and money laundering.

27 September: [David Santana of Reading, MA](#), pleaded guilty to one count of conspiracy to commit health care fraud. As owner of Conclave Media and Nationwide Health Advocates, Santana worked with telemarketing firms that targeted Medicare beneficiaries to generate orders for medically unnecessary DME and genetic tests. Santana faces up to 10 years in prison and a fine of up to \$250,000.

29 September: [South Carolina physician Moustafa Moustafa](#) and his medical practice, South Carolina Nephrology and Hypertension Center Inc., agreed to pay about \$586,000 to resolve allegations that they referred patients for laboratory testing in return for illegal kickbacks. The illicit remuneration allegedly took the form of payments for purported office space rental and phlebotomy services, free clinical staff, and phony consulting fees.

2 October: Exact Sciences subsidiary [Genomic Health](#) agreed to pay \$32.5m to resolve allegations that the company falsely billed Medicare for tests used to treat and diagnose cancer payments. Under Medicare's 14-day rule, labs cannot bill directly for tests ordered within 14 days of the patient's discharge from the hospital. Instead, those tests should be covered through lump-sum payments made to the hospital. Genomic reportedly encouraged hospitals and physicians to manipulate order dates so that the company would receive direct payments.

3 October: The court ordered [Atlanta-based lab owner Minal Patel](#) to forfeit more than \$187m in health care fraud proceeds. Patel ran LabSolutions, a genetic testing lab that worked with telemedicine firms, patient brokers and call centers to recruit Medicare beneficiaries with calls that falsely stated the genetic tests would be covered by Medicare. With Patel's knowledge, telemedicine doctors signed prescriptions for genetic tests for patients they were not treating. Patel had previously been sentenced to 27 years in prison.

5 October: [Lourdes Navarro of Glendale, CA](#), plead guilty to conspiracy to commit health care fraud and wire fraud for her role in a COVID-19 testing scam. She and a co-conspirator collected nasal swab samples from nursing homes and other community centers, then conducted expensive and medically unnecessary respiratory pathogen panel (RPP) tests even though only COVID-19 tests had been ordered. By billing for the RPP tests, the two collected approximately \$54m from Medicare and other insurers. Navarro is scheduled to be sentenced on 23 January 2024 and faces up to 20 years in prison.

6 October: Physician [Alex Glotser of Metairie, LA](#), was charged with health care fraud for his role in a Medicare telemarketing fraud. Glotser signed prescriptions for medically unnecessary DME and laboratory tests for Medicare beneficiaries he never saw or even spoke to. The scam led to

\$5.6m in false Medicare claims, for which Glotser was paid about \$271,000. If convicted, he faces up to 10 years in prison.

Virginia-based [nurse practitioner Daphne Jenkins](#) was charged with one count of conspiracy to commit health care fraud for her role in a similar scam. Like Glotser, she signed prescriptions for unnecessary genetic tests and DME for Medicare beneficiaries who had been recruited by telemarketing firms, and who Jenkins did not treat. About \$7.8m in false claims were submitted to Medicare as a result. She also faces up to 10 years in prison.

10 October: [Jose Goyos of West Palm Beach, FL](#), was convicted on charges of conspiracy to commit wire fraud and conspiracy to commit money laundering for his part in a Medicare telemarketing plot. Goyos managed a call center that deceived physicians into signing orders for medically unnecessary diagnostics and DME for Medicare beneficiaries; specifically, his division called beneficiaries' primary care physicians and falsely claimed that the beneficiaries were "mutual patients" who had medical conditions that justified the testing, but no testing was performed. The conspiracy submitted a total of \$67m in fraudulent claims to Medicare. Goyos is scheduled to be sentenced on 21 December and faces up to 30 years in prison.

[Cardiac Imaging Inc. and its owner, Sam Kancherlapalli](#), agreed to pay \$85m to resolve False Claims Act allegations. Kancherlapalli reportedly paid referring cardiologists excessive fees for supervising PET scans performed at Cardiac Imaging facilities, which was considered a violation of anti-kickback law. The company paid the physicians \$500 per hour, even for lab time during which they were not at the facility; by contrast, data from [ZipRecruiter.com](#) shows the average cardiologist makes \$173 per hour as of October 2023. Cardiac Imaging and Kancherlapalli also entered into a five-year Corporate Integrity Agreement with the Justice Department, which requires the firm to take enhanced compliance measures.