

Genetic Testing Fraud

A New Wave of Medicine, a New Wave of Enforcement Actions

By Ty E. Howard, Scarlett Singleton Nokes, and Giovanni P. Giarratana



Genetic testing is a burgeoning area of preventative and predictive medicine. Such testing enables greater insight into a patient's unique genetic makeup and, in turn, more tailored and individualized medical decisions. (See Press Release, The White House, Office of the Press Secretary, Fact Sheet: President Obama's Precision Medicine Initiative (Jan. 30, 2015), <https://tinyurl.com/pyzdvekx>; Press Release, National Institutes of Health, NIH Forms Team of Experts to Chart Course for the President's Precision Medicine Initiative Research Network (Mar. 30, 2015), <https://tinyurl.com/ycxnneu>.) Indeed, the federal government has acknowledged

the potential benefits of genetic testing technology and has poured significant resources into researching it. (*Id.*)

Developments in genetic testing technology have made it more accessible to the public, and health care benefit programs are now more likely to cover it—including federal payers. (*Will Health Insurance Cover the Costs of Genetic Testing?* NAT'L LIBR. OF MED. (July. 28, 2021), <https://tinyurl.com/bd382bke>; see also *Medicare Coverage Database: Genetic Testing for Cardiovascular Disease*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Dec. 23, 2021), <https://tinyurl.com/43mk4pp5> (providing coverage parameters for cardiovascular genetic testing); *Medicare Coverage Database:*

BRCA1 and BRCA2 Genetic Testing, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Dec. 4, 2020), <https://tinyurl.com/4huc7upe> (providing coverage parameters for cancer genetic testing for breast and ovarian cancers).) And reimbursements for genetic testing can be significant. But that greater coverage and high reimbursement also have made genetic testing an attractive target for fraud. Government regulators have taken notice, and genetic-testing fraud has become a frequent centerpiece of government enforcement actions, both civil and criminal. (See, e.g., Press Release, U.S. Dep't of Just., Genetic Testing Company and Three Principals Agree to Pay \$42.6 Million to Resolve Kickback and Medical

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Necessity Claims (Oct. 9, 2019), <https://tinyurl.com/2at3hmap> (outlining resolution of civil False Claims Act (FCA) allegations against laboratory owners); Press Release, U.S. Dep’t of Just., Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over \$2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged (Sept. 27, 2019), <https://tinyurl.com/3pcn8teu> (describing criminal charges filed against multiple defendants for genetic testing fraud.)

Below we summarize many of these recent enforcement actions and discuss their common targets and theories. We close with several practical takeaways for businesses and providers to navigate this growing area in health care.

CRIMINAL ENFORCEMENT ACTIONS

Over the past few years, several large-scale government takedowns have included genetic testing. In total, these takedowns have alleged billions of dollars in fraud. Genetic testing fraud cases have been prosecuted across the country, but several districts, including the Southern District of Florida, the District of New Jersey, and the Eastern District of Louisiana, have been particularly active.

2019 takedown. The first takedown involving genetic testing occurred in 2019 and primarily involved cancer genetic and genomic testing (also known as CGx testing). (Genetics and genomics are often used interchangeably but are, in fact, distinct. Genetics is the “study of genes and their roles

in inheritance”; genomics is “the study of all of a person’s genes, . . . including interactions of those genes with each other and with the person’s environment.” *Genetics vs. Genomics Fact Sheet*, NAT’L HUM. GENOME RSCH. INST. (Sept. 7, 2018), <https://tinyurl.com/vd637axu>.)

Specifically, in September 2019, charges were filed against 35 individuals in multiple districts for fraudulently billing Medicare

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to medically unnecessary CGx tests. (*Id.*) According to the government, in many instances, patients who were prescribed CGx tests were either not seen by a physician or had only a brief telephone conversation with a physician prior to the CGx test being prescribed.

2020 takedown. The government’s focus on genetic testing continued in 2020. In September 2020, the U.S. Department



more than \$2.1 billion for CGx testing (hereinafter the 2019 takedown). (Press Release, U.S. Dep’t of Just. (Sept. 27, 2019), *supra*.) Those charged included health care providers and owners of telemedicine, telemarketing, and laboratory companies.

The 2019 takedown was the result of a coordinated federal investigation coined Operation Double Helix that was led by the Health Care Fraud Unit of the Criminal Division’s Fraud Section and the Medicare Fraud Strike Force Team. The investigation targeted schemes in which CGx laboratories were allegedly paying illegal kickbacks to telemedicine doctors to prescribe medically unnecessary CGx tests. As part of the alleged scheme, patients were solicited by telemarketing companies that aggressively marketed CGx testing to vulnerable populations and “allegedly duped” Medicare beneficiaries into agreeing

of Health and Human Services Office of Inspector General, in coordination with state and federal law enforcement, announced another nationwide health care fraud takedown (hereinafter the 2020 takedown), which again included cases involving genetic testing. (*2020 National Health Care Fraud Takedown*, U.S. DEP’T OF HEALTH AND HUM. SERVS., <https://tinyurl.com/4amhmwb2> (last visited Feb. 16, 2023).) The 2020 takedown charged more than 345 defendants in 51 judicial districts with alleged losses totaling more than \$6 billion. (*Id.*) Those charged included telemedicine executives, laboratory owners, marketers, and health care practitioners. Unlike the 2019 takedown, which solely focused on genetic testing fraud, the 2020 takedown focused on “alleged telefraud, or scams that leverage[d] aggressive marketing and . . . telehealth services to commit fraud.” (*Id.*)

According to the government, the alleged telefraud involved marketing networks that “lured hundreds of thousands of unsuspecting individuals into a criminal scheme through telemarketing calls, direct mail, television advertisements, and internet pop-up advertisements.” (*Id.*) To facilitate the fraud, telemedicine companies allegedly paid illegal kickbacks to health care providers to order unnecessary testing, equipment, and medications “without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen.” (*Id.*)



allegations included laboratories paying illegal kickbacks to aggressive marketers and telephysicians who illegitimately ordered genetic tests.

TARGETS, THEORIES, AND THEMES IN CRIMINAL ENFORCEMENT ACTIONS

The takedowns and enforcement activity over the last several years highlight some common targets, theories, and themes in genetic testing fraud cases. The usual targets are (1) marketing companies (usually telemarketing, but some have also included elements of door-to-door marketing, Internet

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2022 takedown. Most recently, in July 2022, another line of health care fraud cases involving alleged genetic testing fraud was announced by the U.S. Department of Justice (hereinafter the 2022 takedown). (Press Release, U.S. Dep’t of Just., Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud (July 20, 2022), <https://tinyurl.com/4nbvnaby>.) The 2022 takedown involved some of the first prosecutions of cardiovascular genetic testing fraud and included criminal charges against 36 defendants in multiple judicial districts for more than \$1.2 billion in losses. Those charged include laboratory owners, telemedicine executives, marketing organizations, and health care providers. The

marketing, and direct marketing at community events and health fairs); (2) telemedicine company owners and their physicians; and (3) laboratory owners.

Theories of liability almost always are based on lack of medical necessity, transactions tainted by kickbacks, or both. And the specific offenses charged are likewise fairly consistent, including health care fraud (18 U.S.C. § 1347); conspiracy to commit health care fraud (18 U.S.C. § 1349); offering, receiving, or paying kickbacks (42 U.S.C. § 1320a-7b); and conspiracy to pay or receive kickbacks (18 U.S.C. § 371).

The alleged schemes usually share many of the same characteristics, typically alleging (1) aggressive marketing tactics to

recruit Medicare beneficiaries to agree to genetic tests; (2) using telemedicine physicians to prescribe the genetic tests without seeing the patient or with little to no interaction with the patient; and (3) laboratories paying illegal kickbacks to the marketers and telemedicine companies/physicians to recruit the patients. A recent Southern District of Florida case, *United States v. Omar Saleh*, Case No. 1:22-cr-20317 (S.D. Fla. July 15, 2022), illustrates these common patterns.

Dr. Omar Saleh was charged on July 15, 2022, with conspiracy to commit health care fraud (18 U.S.C. § 1349), along with alleged co-conspirators Panda Conservation Group, LLC (owner of multiple laboratories and a marketing call center), and Michael Stein (an individual who solicited telemedicine physicians to order genetic tests for Medicare beneficiaries).

The government alleged that Saleh caused the submission of false and fraudulent claims for CGx and cardiovascular genetic testing that were “(a) procured through illegal kickbacks and bribes, (b) medically unnecessary, (c) ineligible for reimbursement, and (d) not provided as represented.” (*Id.*) Specifically, the government alleged that Saleh’s “[c]o-conspirators obtained access to thousands of Medicare beneficiaries’ insurance information and DNA material by causing them to be targeted with deceptive marketing campaigns, including online advertising and telemarketing, that promoted genetic testing.” (*Id.*) Stein then paid Saleh kickbacks to write genetic tests for Panda; Saleh ordered these genetic tests for patients with whom he had no prior relationship and whom he

was not treating for any medical condition, and he did not use the test results for the treatment of the beneficiaries. To support its theories of liability, the government relied on 42 U.S.C. § 1395y(a)(1)(A), which states that Medicare does not cover diagnostic testing that is “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” It also relied on 42 C.F.R. § 410.32(a), which provides,

all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. . . . Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

CIVIL ENFORCEMENT ACTIONS

The government has also addressed alleged misconduct involving genetic testing via civil enforcement. As usual, the government has primarily used the FCA in such matters. As in the criminal context, most civil actions involve allegations of (1) ordering medically unnecessary genetic tests and (2) inducing health care providers to give referrals through illegal kickbacks. (While the Anti-Kickback Statute (AKS) is a criminal statute, the government often uses alleged AKS

violations to establish civil liability under the FCA and the Civil Monetary Penalties Law. (See 42 U.S.C. § 1320a-7b(g) (providing that “a claim that includes items or services resulting from a violation of the [AKS] constitutes a false or fraudulent claim” under the FCA); 42 U.S.C. § 1320a-7a(a)(1) (providing that it is a violation of the Civil Monetary Penalties Law to present

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submitted claims for medically unnecessary pharmacogenetic (PGx) testing. (Press Release, U.S. Dep’t of Just., Genetic Testing Company and Three Principals Agree to Pay \$42.6 Million to Resolve Kickback and Medical Necessity Claims (Oct. 9, 2019), <https://tinyurl.com/2at3hmap>.) While CGx involves genetic testing specifically related to cancer predisposition, PGx tests



a claim to the government “for a medical or other item or service . . . [when] the person knows or should know the claim is false or fraudulent.”.)

For example, in February 2019, a Canadian laboratory, GenomeDx Biosciences Corp., entered a \$1.99 million settlement with the Department of Justice to resolve FCA allegations that it was billing Medicare for medically unnecessary CGx tests. (Press Release, U.S. Dep’t of Just., Genetic Testing Company Agrees to Pay \$1.99 Million to Resolve Allegations of False Claims to Medicare for Medically Unnecessary Tests (Feb. 11, 2019), <https://tinyurl.com/mrsfnz4t>.) The CGx tests at issue were for prostate cancer patients who “did not have risk factors necessitating” the CGx tests. (*Id.*)

In October 2019, another laboratory, UTC Laboratories, Inc., agreed to pay \$42.6 million to resolve allegations that it was paying illegal kickbacks and

are administered to determine how a patient’s genetic makeup may affect his or her response to certain medications. (*Pharmacogenomics in Patient Care*, MAYO CLINIC, <https://tinyurl.com/4jm7b9wr> (last visited Feb. 16, 2023).) The illegal kickbacks at issue were twofold: (1) UTC paid kickbacks to physicians to order PGx tests “in return for their participation in a clinical trial known as Diagnosing Adverse Drug Reactions Registry” (Press Release, U.S. Dep’t of Just. (Oct. 9, 2019), *supra*); and (2) UTC paid kickbacks to entities and individuals for referrals of medically unnecessary PGx tests. As a part of the settlement, UTC Laboratories agreed to a 25-year exclusionary period from participating in any federal health care program.

More recently, in January 2022, UC San Diego Health agreed to pay the Department of Justice close to \$3 million to resolve allegations that it ordered

and submitted referrals for medically unnecessary genetic tests performed by CQuentia Labs and paid by Medicare in violation of the FCA, the Civil Monetary Penalties Law, and the Program Fraud Civil Remedies Act. (See Press Release, U.S. Dep’t of Just., UC San Diego Health Pays \$2.98

Providers must stay current on evolving reimbursement rules for telemedicine.

Million to Resolve Allegations of Ordering Unnecessary Genetic Testing (Jan. 11, 2022), <https://tinyurl.com/5cvxx5dm>; UC San Diego Health and U.S. Dep’t of Just. Settlement Agreement (Nov. 23, 2021), <https://tinyurl.com/2hsrwfpv>.) Specific details related to why the government believed the tests were medically unnecessary were not provided in the Department of Justice’s announcement or the parties’ settlement agreement. However, a statement by UC San Diego Health asserted the false claims were a result of issues related to one of its “technology providers” and “order[ing] tests from a company that then allegedly made false claims about those orders.” (Kristina Davis, *UC San Diego Health Pays \$2.98M Settlement Over Claims of Unnecessary Genetic Testing*, SAN DIEGO TRIBUNE (Jan. 11, 2022), <https://tinyurl.com/2p8whes9>.)

PRACTICAL TAKEAWAYS

Given the government’s robust enforcement to date, businesses, providers, and other stakeholders

who work with CGx, PGx, and related testing or laboratory work need to be on guard. While risks cannot be completely avoided, several basic steps can help companies and individuals minimize those risks, including:

- Scrutinize contractual arrangements with business associates and marketers to ensure compliance with the AKS and the Civil Monetary Penalties Law. These laws are nuanced and, often, not intuitive.
- Ensure that any genetic tests ordered are (1) by a physician with an established physician-patient relationship, (2) medically necessary, and (3) properly reimbursable. Medical necessity should be well-documented within patients’ records.



Ty E. Howard is a partner and chair of Bradley Arant Boult Cummings LLP’s Government Enforcement and Investigations Practice Group in Nashville, Tennessee. He draws on his 20 years’ experience as a federal and state prosecutor (where he investigated and prosecuted some of Tennessee’s largest fraud cases) and a leading defense lawyer to assist clients with white-collar criminal defense, False Claims Act matters, sensitive internal investigations, and high-profile litigation.



Scarlett Singleton Nokes is a partner in Bradley Arant Boult Cummings LLP’s Government Enforcement and Investigations Practice Group in Nashville. She draws on her deep experience combatting health care fraud as a federal prosecutor to represent clients in a range of matters related to the health care sector, internal investigations, risk analysis, government investigations, white-collar criminal defense, regulatory and compliance issues, civil litigation, and enforcement actions.



Giovanni P. Giarratana is an associate in Bradley Arant Boult Cummings LLP’s Government Enforcement and Investigations Practice Group in Tampa, Florida. He assists clients in civil and criminal investigations, enforcement actions, and compliance issues across various industries. He also represents clients in complex litigation and has experience litigating issues related to securities fraud, shareholder disputes, breach of contract, employment discrimination, and patent infringement.

- If telehealth services are utilized, stay current on the evolving reimbursement rules for telemedicine and ensure the underlying requirements for appropriately billing such tests are met.
- Regularly audit for potential outliers to assess for noncompliance.
- Consult with experienced counsel for compliance issues, preferably at the outset of a new venture, but especially if government scrutiny is suspected.

This article is an updated and expanded version of the authors’ article “Genetic Testing Fraud: The Government’s Continued Interest,” 17 ABA eSOURCE (June 1, 2021), <https://tinyurl.com/bde4muwm>. ■