

# Genetic Testing Fraud: The Government's Continued Interest

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## General Background and Enforcement Trends

Cancer genetic (CGx)<sup>1</sup> and pharmacogenetic (PGx)<sup>2</sup> testing are part of a new wave of preventive medicine. These tests assess an individual's DNA sequencing to determine the individual's (1) predisposition for certain types of cancers and response to certain cancer treatments (CGx testing); and (2) ability to metabolize certain medications and, thus, how effective a medication will be for that individual (PGx testing). In recent years, these tests have become increasingly more accessible to consumers, a fact that has not gone unnoticed by the government.

In fact, in September 2019, the genetic testing industry was at the center of one of the largest healthcare fraud schemes ever charged. The investigation, known as "Operation Double Helix," resulted in the indictment of 35 defendants who were associated with telemedicine companies and laboratories for fraudulently billing Medicare for over \$2.1 billion for genetic testing.<sup>3</sup>

The government's continued focus on the genetic testing industry has continued through the COVID-19 pandemic. Most recently, in September 2020, the Department of Health and Human Services' Office of Inspector General, in coordination with other federal and state agencies and law enforcement, participated in a massive healthcare fraud takedown (the "2020 National Health Care Fraud Takedown"), which resulted in charges for 345 defendants in 51 judicial districts for over \$6 billion in alleged fraud.<sup>4</sup> Among the defendants charged were those involved with genetic testing. The focus of the 2020 National Health Care Fraud Takedown was on what the government called "telefraud, or scams that leverage aggressive marketing and so-called telehealth services to commit fraud."<sup>5</sup> According to the government, hundreds of thousands of unsuspecting consumers were "lured" by unscrupulous marketing tactics, resulting in telemedicine practitioners ordering medically unnecessary services, equipment, and tests, including genetic testing.<sup>6</sup> While the 2020 National Health Care Fraud Takedown was not

specifically focused on the genetic testing industry, it ensnared multiple defendants associated with the industry and genetic testing laboratories.<sup>7</sup>

## Major Players, Common Theories of Liability, and a Recent Case Example

Thus far, the factual allegations underlying the genetic testing cases pursued by the government look very much the same. The three major players usually include (1) telemarketing companies; (2) telemedicine companies; and (3) laboratories. And the most common theories of liability pursued by the government are under the general healthcare fraud statute, 18 U.S.C. § 1347, and the Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) (AKS).

To support these theories of liability, the government usually alleges that the financial arrangements between these major players were tainted by illegal kickbacks, the genetic tests ordered were not medically necessary, or both. Under Medicare regulations, diagnostic testing “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.”<sup>8</sup> Relying on this regulatory framework, the government’s medically necessary theory is twofold: (1) the tests are not ordered by a treating physician; and (2) the tests are not ordered for the treatment or management of a beneficiary’s specific medical problem. In many of the cases pursued by the government, a telemedicine physician is responsible for ordering the genetic test. The government usually alleges that (1) the telemedicine physician did not have an adequate doctor-patient relationship with the beneficiary, often interacting with the beneficiary only on a brief phone call, and (2) the test was not medically necessary.

The recent conviction of Andre Scott in the Middle District of Florida illustrates these common theories. In January 2021, Mr. Scott, the owner of a telemarketing call center in the Orlando area, was convicted of multiple counts of healthcare fraud and violations of the AKS for his role in a genetic testing fraud scheme. According to the evidence at trial, Mr. Scott used aggressive telemarketing tactics to lure Medicare beneficiaries to agree to genetic testing. Once the beneficiaries agreed to take the test, Mr. Scott then paid kickbacks to telemedicine companies to have telemedicine physicians write orders for the genetic tests. These telemedicine physicians were not the beneficiaries’ treating physicians and, in some cases, did not speak to the beneficiaries at all. Mr. Scott would then broker the tests to a laboratory for which he was paid an illegal kickback from the laboratory. To conceal the illegal kickbacks he was receiving, Mr. Scott submitted invoices to the laboratories that showed he and other marketers were being paid on an

hourly basis.<sup>9</sup> Other marketers who were connected to Mr. Scott and the laboratories who were receiving referrals from them have also found themselves in the government's crosshairs. Many of them have pleaded guilty.<sup>10</sup>

While Mr. Scott was just recently convicted and his case is pending appeal, his indictment was part of the initial major crackdown on the genetic testing industry in September 2019.<sup>11</sup>

Allegations in more recent cases from the 2020 National Health Care Fraud Takedown are nearly identical.<sup>12</sup>

## Takeaways

Genetic testing fraud will continue to be a priority for the government. In light of the recent cases and trends, providers and their counsel should consider the following:

- Carefully review all present and future arrangements with marketers, business associates, and healthcare providers to avoid any potential AKS violations. The law relating to kickbacks is highly fact specific and not always intuitive. Even ostensibly benign payments can be considered illegal remuneration under certain circumstances.
- Ensure that all office visits for ordering of tests are properly reimbursable, and document medical necessity for each and every test.
- The above guidance is particularly true for any tests ordered through a telehealth visit. Stakeholders should be especially mindful of the changing rules regarding telehealth (under both state and federal law) and ensure that services rendered or referred via telehealth visits satisfy the current rules for reimbursement.

- 1 Nat'l Cancer Institute, *Genetic Testing for Inherited Cancer Susceptibility Syndromes* (Mar. 15, 2019), <https://www.cancer.gov/about-cancer/causes-prevention/genetics/genetic-testing-fact-sheet>.
- 2 Mayo Clinic, *Precision Medicine and Pharmacogenomics* (Sept. 3, 2020), <https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/personalized-medicine/art-20044300>.
- 3 Dept of Justice, *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://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against>.

- 4 U.S. Dep't of Health and Human Services, *2020 National Health Care Fraud Takedown* (last updated Mar. 4, 2021), <https://oig.hhs.gov/newsroom/media-materials/2020takedown/>.
- 5 U.S. Dep't of Health and Human Services, *2020 National Health Care Fraud Takedown Factsheet*, available at [https://oig.hhs.gov/documents/root/230/2020HealthCareTakedown\\_FactSheet\\_9dtlhW4.pdf](https://oig.hhs.gov/documents/root/230/2020HealthCareTakedown_FactSheet_9dtlhW4.pdf).
- 6 *Id.*
- 7 For a breakdown of where the cases from the 2020 National Health Care Fraud Takedown were charged or indicted, see Dep't of Justice, *2020 National Health Care Fraud and Opioid Takedown: Court Documents* (last updated Nov. 23, 2020), <https://www.justice.gov/criminal-fraud/hcf-2020-takedown/court-documents>.
- 8 42 C.F.R. § 410.32(a).
- 9 Dep't of Justice, *Patient Recruiter Convicted in \$2.8 Million Telemedicine Scheme Against Medicare* (Jan. 11, 2021), <https://www.justice.gov/opa/pr/patient-recruiter-convicted-28-million-telemedicine-scheme-against-medicare>.
- 10 See, e.g., *U.S. v. Manuel Andres Larenas*, Case No. 6:20-cr-33-ORL, at Dkt. Nos. 3, 52 (M.D. Fla.); *U.S. v. Christopher Miano*, Case No. 0:19-cr-60276-AHS, at Dkt. Nos. 27–28 (S.D. Fla.); *U.S. v. Ravitej Reddy*, Case No. 2:19-cr-00357-WSS, at Dkt. No. 9 (W.D. Pa.); see also Dep't of Justice, *Pittsburgh-Area Lab Owner Pleads Guilty to Multiple Kickback Conspiracies in Connection with Almost \$130 Million in Medicare Claims for Genetic Testing* (Jan. 10, 2020), <https://www.justice.gov/usao-wdpa/pr/pittsburgh-area-lab-owner-pleads-guilty-multiple-kickback-conspiracies-connection>.
- 11 See *supra* n. 3.
- 12 For general case descriptions from the 2020 National Health Care Fraud Takedown, see Dep't of Justice, *2020 National Health Care Fraud and Opioid Takedown: Case Descriptions* (last updated Sept. 30, 2020), <https://www.justice.gov/criminal-fraud/hcf-2020-takedown/case-descriptions>.

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