

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

THE UNITED STATES OF AMERICA)	
)	
Plaintiff,)	Civil Action No. 25-_____
)	
v.)	COMPLAINT
)	
SHAYASTA S. MUFTI,)	JURY TRIAL DEMANDED
)	
Defendant.)	

COMPLAINT OF THE UNITED STATES OF AMERICA

The United States of America, by and through Dylan J. Steinberg, the Acting United States Attorney for the District of Delaware, and Jacob Laksin, Assistant United States Attorney for the District of Delaware, alleges as follows:

I. INTRODUCTION

1. The United States of America (“United States”) brings this action pursuant to the False Claims Act (“FCA”), 31 U.S.C. §§ 3729 *et seq.*, against Dr. Shayasta S. Mufti (“Dr. Mufti” or “Defendant”) to recover damages suffered as a result of Dr. Mufti’s unlawful conduct, including causing the submission of hundreds of false claims to Medicare for diagnostic genetic cancer screening tests that were medically unnecessary and ineligible for Medicare reimbursement.

2. Dr. Mufti is a licensed physician and board certified in internist, a Delaware resident, and an enrolled Medicare provider.

3. As described below, during an eight-month period between April of 2019 and November of 2019, Dr. Mufti participated in a scheme to illegally profit from genetic cancer testing by knowingly causing the submission of hundreds of false and fraudulent claims to Medicare for genetic cancer screening tests that were medically unnecessary and ineligible for

reimbursement, and by knowingly making or causing to be made hundreds of false and fraudulent records and statements material to the payment of those claims.

4. Dr. Mufti contracted with a telemedicine company called MySpecialistMD, Network, LLC (“MSMD”) and used their online telemedicine platform to electronically approve consultations for genetic testing for over one hundred Medicare beneficiaries with whom she had no prior physician-patient relationship, whom she never examined or evaluated, and with whom she had only brief, if any, interaction.

5. Dr. Mufti knew, recklessly disregarded, or was deliberately ignorant of the fact that her approvals of these consultations resulted in the generation of false and fraudulent documentation bearing her electronic signature, which falsely attested that the genetic tests were medically necessary and were ordered as part of a legitimate physician-patient relationship.

6. This documentation included attestations, signed by Dr. Mufti, that (1) the genetic tests were medically necessary, (2) the beneficiaries were her “patients,” (3) that Dr. Mufti would use the test results to make patient-specific treatment decisions in order to further “pursue care” for her patients, and that (4) she was “legally authorized” to order tests for them. These attestations were false and fraudulent.

7. In fact, Dr. Mufti knew, recklessly disregarded, or was deliberately ignorant of the fact that she was not authorized to order genetic testing for any of the beneficiaries because, as she well knew, she was not their treating physician, they were not her patients, she had never examined or evaluated them, and she had never consulted with them or had only brief telemedicine interactions before ordering testing. Likewise, Dr. Mufti knew that she did not review their test results, had no intention to use the results to manage any of their medical conditions, and, indeed, was unaware whether the tests had even been performed.

8. Clinical laboratories relied on the false and fraudulent documentation Dr. Mufti created or caused to be created to process the genetic tests and submit false or fraudulent claims to Medicare for reimbursement of genetic testing services that were not medically necessary.

9. As a direct and foreseeable result of Dr. Mufti's conduct, Medicare in 2019 was billed over \$1.7 million and paid \$564,985.87 for claims submitted by clinical laboratories for medically unnecessary genetic tests that would not have been—and could not have been—performed or presented for payment to Medicare but for the false and fraudulent genetic testing orders and supporting documentation that Dr. Mufti created or caused to be created.

II. JURISDICTION

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a plaintiff pursuant to the FCA.

11. This Court may exercise personal jurisdiction over Dr. Mufti under 31 U.S.C. § 3732(a) because Dr. Mufti resides in and/or at all relevant times resided in the District of Delaware, and because many of the acts proscribed by the FCA occurred in this District.

12. Venue is proper in the District of Delaware under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a), because Dr. Mufti resides in and/or at all relevant times resided in this District, and because many of the acts proscribed by the FCA occurred in this District.

III. PARTIES

13. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), which, through the Centers for Medicare and Medicaid Services ("CMS"), administers the Medicare program.

14. Defendant Dr. Shayasta S. Mufti resides in and/or at all times relevant to the Complaint resided in Bear, Delaware, and is a physician licensed to practice medicine in Delaware.

IV. LEGAL AND REGULATORY FRAMEWORK

A. The False Claims Act

15. The False Claims Act is the primary tool used by the United States to combat false claims and fraud against the government and to protect the public fisc. The FCA allows the United States to recover funds fraudulently obtained through various federal programs and to hold individuals or entities accountable for making false or fraudulent claims to the government.

16. The Supreme Court has held that the FCA's provisions must be construed broadly to reach "all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White*, 390 U.S. 228, 232 (1968).

17. The FCA provides, in pertinent part, that any person who:

(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim ...

is liable to the United States for three times the amount of damages which the Government sustains, plus a mandatory civil penalty of not less than \$14,308 and not more than \$28,619 per violation. 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.

18. For purposes of the FCA, the terms "knowing" and "knowingly"

"(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud. . . ."

31 U.S.C. § 3729(b)(1).

19. The term "claim" includes any

request or demand . . . for money or property . . . that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or

other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program . . . and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(b)(2).

20. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

21. "A claim can be proven 'false' in two ways: factually, when the facts contained within the claim are untrue, and legally, when the claimant falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *United States v. Care Alternatives*, 952 F.3d 89, 96 (3d Cir. 2020) (alterations and quotation marks omitted).

B. The Medicare Program

22. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395, *et seq.*

23. HHS is responsible for administering and supervising the Medicare program. CMS is the HHS component directly responsible for administering the Medicare program.

24. Medicare entitlement is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Medicare-insured individuals are commonly referred to as Medicare "beneficiaries."

25. Medicare provides coverage for items and services that are reasonable and necessary to diagnose or treat an illness or injury or to improve a malformed body member. 42 § U.S.C. 1395y(a)(1)(A). No payment may be provided under Medicare if medical necessity is not substantiated. *Id.*

C. Medicare Part B

26. Medicare has four parts: A, B, C, and D. 42 U.S.C. §§ 1395c-1395i. Medicare Part B covers outpatient care, including, *inter alia*, physician services and ancillary services, such as clinical laboratory services, furnished by physicians and other providers and suppliers.¹ 42 U.S.C. § 1395k.

27. As alleged herein, Dr. Mufti caused to be submitted false claims under Medicare Part B.

28. Medicare Part B covers only those services, including diagnostic laboratory services, which are reasonable and necessary for the diagnosis or treatment of an illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) (“[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]”); 42 C.F.R. § 411.15(k) (disallowing payment for certain types of services, tests, and examinations that are not “reasonable and necessary”).

29. Medicare Part B providers must certify that the services they provide are medically necessary. 42 C.F.R. § 424.24(g)(1). Services that are not reasonable and necessary are ineligible for Medicare reimbursement. *Id.*

30. Health care providers who wish to submit claims for Medicare reimbursement must enroll in the Medicare program. As part of the enrollment process, and as a material condition of participation in Medicare, medical providers must certify compliance with Medicare regulations, program instructions and conditions. *See* 42 C.F.R. § 424.510. Enrolled providers also must

¹ In the relevant regulations, physicians and other practitioners are generally referred to as “suppliers” in the Medicare program, rather than “providers.” *See* 42 C.F.R. § 400.202. This Complaint nonetheless uses the common term “provider” to refer to individual practitioners.

certify that they meet, and will continue to meet, the requirements of the Social Security Act as well as Medicare regulations, and the conditions regarding coverage for services for which they seek reimbursement. 42 C.F.R. § 424.516(a)(1).

31. To participate in the Medicare program, providers must submit a Medicare Enrollment Application, Form CMS-855B.

32. Form CMS-855B requires, among other things, that signatories certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to me The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf> (last visited May 22, 2025).

33. Medical providers have a duty to familiarize themselves with the statutes, regulations, and guidelines regarding coverage and reimbursement for the Medicare services they provide. *See Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

34. As a Medicare enrolled provider, Dr. Mufti certified that she understood and would comply with Medicare laws, regulations, and program instructions. By signing the certification statement, Dr. Mufti also understood that she would “not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.” Dr. Mufti further certified that she understood that Medicare payment was conditioned on her truthful certification as well as on her compliance with all Medicare laws, regulations, and program instructions.

35. By ordering genetic testing for a Medicare beneficiary, Dr. Mufti certified that the item or service met the requirements for coverage by Medicare, including that such item or service was “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a)(1)(A).

36. To obtain Medicare reimbursement, providers and suppliers are required to have specific documents and information from the patient-physician encounter.

37. For example, each request for payment or bill submitted for an item or service payable under Medicare Part B includes the name and unique physician identification number for the referring physician. 42 U.S.C. § 1395l(q)(1).

38. The unique physician identification number is known as the National Provider Identifier (“NPI”). NPI is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

39. To obtain Medicare reimbursement for the genetic tests ordered by Dr. Mufti, diagnostic laboratories submitted claims for payment to Medicare. Dr. Mufti was the referring physician for each of the 103 beneficiaries for whom claims for reimbursement for genetic testing were submitted to Medicare, and each of those claims included Dr. Mufti’s name and NPI number.

D. Medicare Requirements for Genetic Cancer Screening Testing

40. Medicare will not reimburse claims for diagnostic testing, including genetic cancer screening 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.” 42 U.S.C. § 1395y(a)(1)(A).

41. Physicians and medical providers who seek Medicare reimbursement for such testing must “certify the necessity of the services and, in some instances, recertify the continued need for those services.” 42 C.F.R. § 424.10(a).

42. Except for certain limited statutory exceptions, which are not applicable here (*e.g.*, screening mammography, colorectal cancer screening tests, prostate cancer screening tests), Medicare also does not cover “[e]xaminations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury.” 42 U.S.C. § 411.15(a)(l).

43. Even if a particular diagnostic test is necessary for the treatment or diagnosis of a specific illness or injury or improve the functioning of a malformed body member, Medicare will not reimburse claims for any diagnostic test unless the test is ordered by the treating physician who (i) has a direct physician-patient relationship with the beneficiary and (ii) uses the test results in the clinical management of the beneficiary.

44. Medicare regulations mandate that diagnostic testing, which includes genetic cancer 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. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.” 42 CFR § 410.32(a)

45. The medical necessity of each diagnostic test must be individually assessed and documented in each patient’s medical chart. 42 C.F.R. § 410.32(a), (d)(2).

46. Genetic cancer testing (also known as cancer genomic testing or “CGx” testing) is a type of diagnostic laboratory testing that uses DNA sequencing to determine an individual’s risk of developing various types of hereditary cancers, such as, for example, breast, ovarian, colorectal, and pancreatic cancers.

47. CGx testing is not a method of diagnosing whether an individual presently has cancer. Rather, the medical utility of CGx testing lies in its ability to inform individuals and their

treating providers about their genetic predispositions, which can guide personalized cancer screening, prevention strategies, and targeted treatment decisions.

48. Medicare covers CGx testing only in limited circumstances. Like other diagnostic testing, CGx testing is ineligible for reimbursement unless it is reasonable and medically necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member, 42 U.S.C. § 1395y(a)(1)(A).

49. CGx testing also is not covered by Medicare unless it is ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results of the testing to manage the beneficiary's specific medical problem, 42 CFR § 410.32(a).

50. Additionally, Medicare does not cover CGx testing for screening purposes. 42 C.F.R. § 411.15(a)(1).

51. Medicare further limits coverage for CGx testing through a National Coverage Determination ("NCD"). An NCD is a decision made by CMS about whether Medicare will cover a specific medical service or procedure nationwide. CMS has issued NCD 90.2 titled "Next Generation Sequencing (NGS)," which governs nationwide coverage for CGx tests.² Under the version of NCD 90.2 in effect in 2019, Medicare would reimburse claims for CGx testing only if, among other requirements, (1) the beneficiary had been diagnosed with cancer and had decided to seek further cancer treatment, (2) the CGx test was ordered by a treating physician, and (3) the results of the test were provided to the treating physician (4) to manage the beneficiary's medical condition and to guide specific treatment options for the beneficiary.

52. At all times relevant to the Complaint, the CGx testing ordered by Dr. Mufti was ineligible for Medicare reimbursement because Dr. Mufti was not the treating physician for any of

² <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=372&ncdver=1&>

the Medicare beneficiaries for whom she ordered testing and the testing was not used for the diagnosis or treatment of any illness or injury those beneficiaries may have had.

53. CGx tests Dr. Mufti ordered or caused to be ordered for these beneficiaries also were ineligible for Medicare reimbursement pursuant to the NCD because many of the beneficiaries did not have cancer and were not seeking cancer treatment, and the results of the CGx tests were not used to treat them for cancer or, manage their medical conditions, or inform treatment options. Indeed, Dr. Mufti never saw or reviewed the results of any of the CGx tests she ordered or caused to be ordered, never followed up with any of the beneficiaries about their test results, never discussed their test results with them, and was unaware whether any of the tests had even been done.

E. Medicare and Telemedicine

54. Telemedicine provides a means of connecting patients to physicians by using telecommunications technology, such as a telephone or the internet, to interact with a patient.

55. Legitimate telemedicine companies provide telemedicine or telehealth services to individuals by employing doctors and other health care providers, and pay providers a fee to conduct virtual consultations with patients who have requested such consultations or are seeking medical services. Telemedicine companies then either bill a patient's insurance, including Medicare, for the consultation, or bill the patient directly.

56. By contrast, in telemedicine fraud schemes, telemedicine companies often hire providers to review and approve medically unnecessary services, such as genetic testing, typically for elderly or disabled patients who have not sought out any medical services, but instead have been contacted by marketers who obtained their personal information.

57. In these telemedicine fraud schemes, the telemedicine companies frequently do not bill insurance or patients for a consultation, because no legitimate consultation occurred. Instead,

after the testing is approved by their contracted health care providers, the telemedicine companies refer the testing to clinical laboratories, who process the genetic tests and bill Medicare directly for the tests. The health care providers in turn are compensated by the telemedicine companies, who often pay them a flat fee for every purported consultation.

V. DR. MUFTI'S FRAUDULENT SCHEME

A. Genetic Testing Fraud Schemes

58. HHS's Office of Inspector General ("HHS-OIG") has repeatedly warned providers and the public about various fraudulent genetic testing schemes.

59. In 2019, federal agencies, including HHS and the Department of Justice ("DOJ"), identified cancer genetic testing fraud as a significant and growing threat to the integrity of the Medicare program. In September 2019, HHS-OIG published "Fraud Alert: Genetic Testing Scam," which explained how such fraud schemes work:

Genetic testing fraud occurs when Medicare is billed for a test or screening that was not medically necessary and/or was not ordered by a Medicare beneficiary's treating physician. Scammers are offering Medicare beneficiaries "free" screenings or cheek swabs for genetic testing to obtain their Medicare information for identity theft or fraudulent billing purposes.³

60. The fraud alert was issued in conjunction with a nationwide DOJ takedown in which 35 individuals associated with telemedicine companies and CGx testing laboratories were arrested and charged with health care fraud and other offenses for their role in billing Medicare over \$2 billion for CGx tests.⁴ The charges included allegations that a number of medical providers contracted with telemedicine companies to authorize bogus orders for CGx tests for Medicare beneficiaries, and attested that the tests were medically necessary, even though the

³ <https://oig.hhs.gov/fraud/consumer-alerts/fraud-alert-genetic-testing-scam>

⁴ <https://www.justice.gov/archives/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against>

providers did not treat the beneficiaries, had no physician-patient relationship with them, and often did not even speak with the beneficiaries for whom they ordered tests. *Id.*

61. In April 2021, HHS-OIG issued another Fraud Alert, which stated:

In the alleged scheme, recruiters (aka marketers) get a Medicare beneficiary to take a genetic test. The recruiter then gets a doctor to sign off on the genetic test so a lab will process the test. The recruiter pays the doctor a kickback in exchange for ordering the test. Then the lab processes the test and bills Medicare. Medicare reimburses the lab for the test and the lab shares the proceeds of that payment with the recruiter.⁵

B. Dr. Mufti's False and Fraudulent Genetic Testing Orders

62. As detailed below, between April 2019 and November 2019, Dr. Mufti caused the submission of false or fraudulent claims when she ordered expensive and medically unnecessary CGx tests for 103 Medicare beneficiaries.

63. Pursuant to Medicare rules, these tests were medically unnecessary because, among other reasons, Dr. Mufti (1) was not a treating physician for any of the beneficiaries, (2) did not examine or often even speak with the beneficiaries before referring them for genetic testing, and (3) did not use the results of the genetic tests to manage their clinical care.

64. Dr. Mufti became an enrolled Medicare provider in or around 2012. In so doing, Dr. Mufti certified that she would comply with all Medicare rules, regulations, and program instructions applicable to her, including that she would not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare.

65. Dr. Mufti first began providing telemedicine services in or around 2016.

66. In 2017, Dr. Mufti contracted with MSMD to provide telemedicine services. At all times relevant to the Complaint, MSMD was an Ohio-based telemedicine company that used a

⁵ <https://oig.hhs.gov/newsroom/media-materials/media-materials-nationwide-genetic-testing-fraud/>

network of medical providers, including Dr. Mufti, to provide telehealth consultations to patients using its technology platforms.

67. In March 2019, Dr. Mufti was approached by MSMD to begin ordering CGx testing for Medicare beneficiaries using MSMD's online telemedicine platform, or portal ("MSMD portal").

68. During the course of her work for MSMD, Dr. Mufti used the MSMD portal to order or cause to be ordered CGx tests for 103 Medicare beneficiaries, including beneficiaries B.D., E.A., A.S., M.F., and J.H., as further described below.

69. In preparation for ordering genetic tests, MSMD provided Dr. Mufti a video tutorial addressed to participating telemedicine providers that explained, in step-by-step fashion, the process by which providers would order genetic testing using the MSMD portal.

70. The video tutorial explained that providers would first need to log into the MSMD portal, which would allow them to view queue of patient "consults" for genetic testing. There, providers would be able to view, among other documents and information, intake forms for patients, review suggested diagnostic codes for ordering genetic testing, and complete a "SOAP" (subjective, objective, assessment and plan) note documenting their purported interactions with patients.

71. Once providers entered a SOAP note and electronically "approved" the consultation for genetic testing in the MSMD portal, all of the information needed to order the testing and submit claims for payment to Medicare—such as patient information, including their unique Medicare beneficiary numbers, ordering physician information, and an electronic physician signature—would be electronically generated and applied to a series of forms, which included order forms for genetic testing and related supporting documentation, such as certifications of medical necessity.

72. This genetic testing documentation was then transmitted to diagnostic laboratories, who would use the documentation to process the genetic tests and submit claims for reimbursement to Medicare for the testing.

73. In April of 2019, the founder of MSMD, Dr. Jonathan Wiesen, provided Dr. Mufti with stock clinical language that she was to include in her SOAP notes to make it appear that the CGx tests were requested by the beneficiary, prescribed by the beneficiary's treating provider as part of a clinical "plan," and would be used to manage their medical treatment.

On Thu, Apr 4, 2019 at 9:39 PM Jonathan Wiesen <jwiesen@myspecialistmd.com> wrote:

The patient's main complaint is: given their personal and family history, would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition.

Specifically: Personal/Family History of .

The plan is to order a genetic testing battery to evaluate for disease risk as an efficient and effective way to analyze multiple genes and potential mutations that can be associated with

particular conditions or individual health risks. In my expert opinion these tests would help in the management of this patient.

Jonathan Wiesen MD

Inline image 2

MySpecialistMD

Cell: (551) 486 - 6214

www.myspecialistmd.com

74. Consistent with Dr. Wiesen's directive, when ordering genetic testing through the MSMD portal, Dr. Mufti stated in her SOAP notes that the "patient's main complaint is: given their personal and family history, [the patient] would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition." Dr. Mufti also stated in the SOAP notes that her "plan" was "to order a genetic testing battery to evaluate for disease risk," and that these tests "would help in the management of th[e] patient."

75. Dr. Mufti included this purported "plan" in her SOAP notes for each of the 103 beneficiaries for whom she ordered genetic testing. Dr. Mufti signed off on this "plan" even

though, as she knew, the beneficiaries were not Dr. Mufti's "patients," she was not their treating physician, she was not managing their medical conditions, and she never used, and had no intention of using, the results of the CGx tests to determine their clinical needs or to otherwise inform their care. Diagnostic laboratories then used these false and fraudulent SOAP notes to justify the submission of claims for genetic testing.

76. The genetic testing documentation that Dr. Mufti created or caused to be created also contained numerous other materially false and fraudulent statements designed to obtain payment from Medicare and make it appear as though the genetic testing was medically necessary and had been ordered by Dr. Mufti in the course of Dr. Mufti's treatment of the beneficiary

77. Documentation for each beneficiary included a "certificate of medical consultation," electronically signed by Dr. Mufti, falsely certifying that the "patient" had been "evaluated" by Dr. Mufti, who had determined that "the plan is to order a genetic testing battery" for the patient, which would "help in the management of this patient."

	
CERTIFICATE OF MEDICAL CONSULTATION	
<small>Shayasta Mufti, MD, MD</small>	
<small>Services provided on behalf of MySpecialistMD Network 30575 Bainbridge Rd Suite 200, Solon, OH 44139, USA PHONE: (216)762-0777 FAX: (312) 241-1980</small>	
Patient Name: [REDACTED]	[REDACTED]
Date of Birth: [REDACTED]	[REDACTED]
This is to certify that a consult for Patient: [REDACTED] was evaluated by clinician on: 2019-09-09	
Physician Encounter Note:	
<small>I spoke with patient over the phone. He reported that he was diagnosed with melanoma in his 50's. His son was diagnosed with melanoma in his 40's. His sister was a smoker and had lung CA. Hence patient would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition.</small>	
<small>The plan is to order a genetic testing battery to evaluate for disease risk as an efficient and effective way to analyze multiple genes and potential mutations that can be associated with particular conditions or individual health risks. In my expert opinion these tests would help in the management of this patient.</small>	
Physician Signature: 	
<small>Date: 2019-09-09</small>	

78. Dr. Mufti knew, recklessly disregarded, or was deliberately ignorant of the fact that this document was false and fraudulent because she was not the treating physician for any of the beneficiaries, they were not her patients, she had not evaluated them, and she did not use, and did not intend to use, the results of the genetic testing to manage any of their medical conditions.

79. The documentation also included clinical laboratory requisition forms for genetic testing signed by Dr. Mufti for each beneficiary that identified Dr. Mufti as the ordering provider and included her NPI and ordered the most “comprehensive”—and expensive—genetic test available.

 <p>Landmark Diagnostics 9350 Kirby Drive, Ste. 150 Houston, TX 77054 Phone: 479-464-0544 Fax: 479-802-6556 CLIA# 45D2084397 landmarkdx.com</p>		<p>Hereditary Cancer Test Requisition Form 35-Gene Test for Hereditary Cancer Risk</p> <p>▼ BARCODE ▼</p> <p>REQUIRED BARCODE STICKER Attach barcode for the kit your patient used.</p> <p>Sample Collection Date (MM/DD/YYYY) 06/13/2019</p>																						
<p>PATIENT INFORMATION</p> <table border="1"> <tr> <td>Patient's First Name</td> <td>Patient's Last Name</td> <td>M.I.</td> <td>Sex</td> <td><input type="checkbox"/> Male <input checked="" type="checkbox"/> Female</td> </tr> <tr> <td>Date of Birth (MM/DD/YYYY)</td> <td>Patient's Address</td> <td colspan="3">City, State, and Zip Eunice LA 70535</td> </tr> <tr> <td>Patient's Email Address (required) noemail@gmail.com</td> <td>Patient's Phone Number</td> <td colspan="3">MRN (optional)</td> </tr> <tr> <td colspan="5">Ancestry (Select all that apply) Caucasian</td> </tr> </table>					Patient's First Name	Patient's Last Name	M.I.	Sex	<input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Date of Birth (MM/DD/YYYY)	Patient's Address	City, State, and Zip Eunice LA 70535			Patient's Email Address (required) noemail@gmail.com	Patient's Phone Number	MRN (optional)			Ancestry (Select all that apply) Caucasian				
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<p>PATIENT INSURANCE INFORMATION</p> <table border="1"> <tr> <td>Insurance Company Name Medicare Plan B</td> <td>Member ID</td> <td colspan="3">Relationship to Patient <input checked="" type="checkbox"/> Self <input type="checkbox"/> Spouse/Partner <input type="checkbox"/> Child <input type="checkbox"/> Other</td> </tr> <tr> <td>Policy Holder's First Name (if not self)</td> <td>Policy Holder's Last Name (if not self)</td> <td colspan="3">Please attach a copy of front and back of insurance card and ID</td> </tr> </table>					Insurance Company Name Medicare Plan B	Member ID	Relationship to Patient <input checked="" type="checkbox"/> Self <input type="checkbox"/> Spouse/Partner <input type="checkbox"/> Child <input type="checkbox"/> Other			Policy Holder's First Name (if not self)	Policy Holder's Last Name (if not self)	Please attach a copy of front and back of insurance card and ID												
Insurance Company Name Medicare Plan B	Member ID	Relationship to Patient <input checked="" type="checkbox"/> Self <input type="checkbox"/> Spouse/Partner <input type="checkbox"/> Child <input type="checkbox"/> Other																						
Policy Holder's First Name (if not self)	Policy Holder's Last Name (if not self)	Please attach a copy of front and back of insurance card and ID																						
<p>ORDERING PROVIDER</p> <table border="1"> <tr> <td>First and Last Name Shayasta Mufti, MD, MD</td> <td>Phone Number</td> <td>Fax Number</td> <td colspan="2">NPI Number</td> </tr> <tr> <td>Email Address support@myspecialistmd.com</td> <td>Address</td> <td colspan="2">City, State, and Zip Bear DE 19701</td> <td></td> </tr> </table>					First and Last Name Shayasta Mufti, MD, MD	Phone Number	Fax Number	NPI Number		Email Address support@myspecialistmd.com	Address	City, State, and Zip Bear DE 19701												
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<p>CANCER PANEL</p> <table border="1"> <tr> <td>Panel:</td> <td>Genes:</td> </tr> <tr> <td><input checked="" type="checkbox"/> Comprehensive</td> <td>APC, ATM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FANCC, HRAS1, MEN1, MET, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTCH, PTEN, RAD50, RAD51, RAD51C, RAD51D, RET, SMAD4, STK11, TP53, VHL</td> </tr> <tr> <td><input type="checkbox"/> BRCA1 and BRCA2</td> <td>BRCA1, BRCA2</td> </tr> <tr> <td><input type="checkbox"/> Breast and Ovarian Cancer</td> <td>ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, RAD51C, RAD51D, TK11, TP53</td> </tr> <tr> <td><input type="checkbox"/> Colorectal, Endometrial and Ovarian Cancer</td> <td>APC, BMPR1A, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, TP53, STK11</td> </tr> <tr> <td><input type="checkbox"/> Lynch Syndrome</td> <td>MLH1, MSH2, MSH6, PMS2, EPCAM</td> </tr> </table>					Panel:	Genes:	<input checked="" type="checkbox"/> Comprehensive	APC, ATM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FANCC, HRAS1, MEN1, MET, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTCH, PTEN, RAD50, RAD51, RAD51C, RAD51D, RET, SMAD4, STK11, TP53, VHL	<input type="checkbox"/> BRCA1 and BRCA2	BRCA1, BRCA2	<input type="checkbox"/> Breast and Ovarian Cancer	ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, RAD51C, RAD51D, TK11, TP53	<input type="checkbox"/> Colorectal, Endometrial and Ovarian Cancer	APC, BMPR1A, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, TP53, STK11	<input type="checkbox"/> Lynch Syndrome	MLH1, MSH2, MSH6, PMS2, EPCAM								
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<p>PATIENT'S PERSONAL HISTORY FAMILY HISTORY OF CANCER</p>																								

80. The requisition forms included certifications, electronically signed by Dr. Mufti as the “ordering physician,” attesting that the genetic tests being ordered were medically necessary, the results of the tests would be used to “determine the patient’s medical management and treatment decisions,” that Dr. Mufti was “legally authorized” to order the test, and that the patient was provided with information about genetic testing and consented to have the testing performed.

CONFIRMATION OF INFORMED CONSENT AND MEDICAL NECESSITY	
<p>The tests ordered are medically necessary for the risk assessment, diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine the patient's medical management and treatment decision. The person listed as the Ordering Physician is legally authorized to order the test(s) requested herein. The patient was provided with information about genetic testing and has consented to have genetic testing performed.</p>	
 06/16/2019	
Ordering Physician Signature 	

81. Dr. Mufti knew, recklessly disregarded, or was deliberately ignorant of the fact that these signed certifications of medical necessity were false because (i) she was not the treating provider for any of the beneficiaries; (ii) she was not legally authorized to order any testing on their behalf; (iii) she had never examined the beneficiaries and made no attempt to determine whether that genetic testing was medically necessary or consistent with Medicare limitations on genetic testing; (iv) she had no intention of using the genetic test results to manage their medical conditions or to inform treatment decisions for the beneficiaries; and (v) she had not provided them with any information about genetic testing or discussed genetic testing with them, and in many cases had no direct interaction with them at all before ordering genetic testing.

82. The genetic testing documentation also included letters of medical necessity signed by Dr. Mufti addressed to insurance claim specialists, purporting to document medical necessity for genetic testing for “my patient,” and stating that the test results would be received by Dr. Mufti and used by her “in order to pursue care for my patient.” Based on these representations, the letter requested “full coverage of my patient’s DNA-based hereditary cancer diagnostic test.”

HEREDITARY CANCER GENETIC TESTING LETTER OF MEDICAL NECESSITY

The genes in the test are warranted to identify the risk for cancer and / or detect cancer early, and to reduce morbidity and mortality. This genetic testing will help estimate my patient's risk to develop (and potentially die of) cancer. It will also directly impact my patient's medical management.

The test will take at least four (4) to six (6) weeks for completion. Therefore, we are requesting that the authorization remain valid for at least 90 days. I request your written, timely response to the laboratory, given the importance of this matter.

Thank you for your time.



Ordering Clinician Signature: _____

Date: 06/16/2019

83. Like the other statements and certifications in the genetic testing documentation that Dr. Mufti created or caused to be created, the representations in this letter were false because Dr. Mufti had no patient-provider relationship with any of the beneficiaries for whom she ordered genetic testing, she was not managing their care, and she did not use, and had no intention of using, the results of the genetic to pursue any care for any of the beneficiaries.

84. Dr. Mufti knew, recklessly disregarded, or was deliberately ignorant of the fact that her conduct in approving the consults for genetic testing using the MSMD portal would result in false documents and genetic testing orders being created, with her electronic signature, and that, based on those false documents, claims for reimbursement of those tests would be submitted to Medicare.

85. Not only was Dr. Mufti not treating any of the beneficiaries for whom she ordered genetic testing, but Dr. Mufti did not speak with, evaluate, or have any direct interaction with many of the beneficiaries for whom she ordered testing.

86. For genetic tests she ordered or caused to be ordered between April 2019 and June 2019, Dr. Mufti did not speak with any of the beneficiaries. It was not until after June 2019, when she had already been ordering genetic testing for approximately two months, that Dr. Mufti first began trying to call the beneficiaries before ordering genetic testing.

87. Even then, Dr. Mufti continued to order genetic testing for beneficiaries even when she was “unable to reach them,” until being instructed by MSMD’s Dr. Wiesen on June 21, 2019, that “from now on” she should “only approve [genetic testing] after speaking with the patient.”

Genomics Telemedicine

Jonathan Wiesen <jwiesen@myspecialistmd.com>
 To: shayasta mufti <shayastamufti@hotmail.com>, Chris Bittel <cbittel@myspecialistmd.com>
 Cc: Vincent Gelardi <vin.gelardi@myspecialistmd.com>

Fri, Jun 21, 2019 at 7:11 AM

Hi Dr. Mufti,

From now on please only approve after speaking with the patient.

Thank you very much for your assistance with this,
 Jonathan

Jonathan Wiesen, MD
 Www.myspecialistmd.com
 +1 (551) 486-6214

From: shayasta mufti <shayastamufti@hotmail.com>
Sent: Friday, June 21, 2019 4:26 AM
To: Chris Bittel
Cc: Jonathan Wiesen; Vincent Gelardi
Subject: Re: Genomics Telemedicine

So a last week when I first started doing the phone calls... I made 3 attempts to call a few patients and was unable to reach them. I then went ahead and approved some consults based on the forms attached.... since that is what we had been doing before. We had been approving (or rejecting) based on the attached forms. Should I go back and edit and reject all those consults?!

Regards,
 Shayasta Mufti

88. Dr. Mufti did not use or intend to use the results of the CGx testing for the clinical management of any of the Medicare beneficiaries she referred for genetic testing. Even if they had wanted to, beneficiaries could not contact Dr. Mufti directly to discuss their test results. Instead, beneficiaries wishing to discuss test results with a physician had to request that a MSMD “associate” schedule a “consultation” with a “physician provider,” or call a general support number for MSMD. Dr. Mufti never discussed the results of any of the CGx tests with any of the beneficiaries for whom she ordered or caused to be ordered CGx testing.

89. Dr. Mufti did not bill Medicare for or seek reimbursement for any of the genetic testing she ordered or caused to be ordered. Instead, MSMD paid Dr. Mufti approximately \$25 for each purported consultation. In total, MSMD paid Dr. Mufti approximately \$15,000 in 2019.

90. Of the CGx tests that Dr. Mufti ordered or caused to be ordered, approximately 76 percent were processed by Landmark Diagnostics, LLC (“Landmark Diagnostics”), a clinical laboratory based in Houston, Texas, which then billed Medicare for those tests.

91. In 2024, the owner and operator of Landmark Diagnostics pleaded guilty to criminal healthcare fraud and agreed to pay over \$27 million to resolve claims that he and his companies, including Landmark Diagnostics, submitted false claims to Medicare for medically unnecessary CGx tests.⁶

92. CGx tests that Dr. Mufti ordered or caused to be ordered were billed to Medicare by diagnostic laboratories like Landmark Diagnostics at a cost of thousands of dollars per test. In total, Medicare paid out \$564,985.87 on claims for CGx testing that Dr. Mufti ordered or caused to be ordered.

Illustrations – Genetic Testing Order for Patient B.D.

93. Patient B.D. provides an illustration of Dr. Mufti’s pivotal role in perpetrating the genetic testing fraud scheme.

94. On June 16, 2019, Dr. Mufti approved an extensive array of CGx testing for B.D., then a 57 year-old Medicare beneficiary who resided in Eunice, Louisiana. Dr. Mufti’s signed certificate of medical consultation for B.D. reflects that Dr. Mufti called B.D. on that date, but that B.D. was unable to tell Dr. Mufti her date of birth because, according to B.D.’s caretaker, B.D. was “disabled.”

⁶ <https://www.justice.gov/usao-sdfl/pr/florida-businessman-daniel-hurt-pay-over-27-million-medicare-fraud-connection-cancer>

95. Dr. Mufti nonetheless approved B.D. for genetic testing through the MSMD portal, which resulted in false and fraudulent orders for genetic testing and supporting documentation bearing Dr. Mufti's electronic signature being created so that genetic testing for B.D. could be performed by a clinical laboratory and billed to Medicare.

96. This false documentation included a certificate of medical consultation, electronically signed by Dr. Mufti, representing that B.D. was her "patient," that Dr. Mufti had "evaluated" her on June 16, 2019, that B.D. "would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition," and stated that the "plan is to order a genetic testing battery to evaluate [B.D.] for disease risk," which would help in the "management of this patient."

Physician Encounter Note:

I called the patient. The patient was unable to tell me her date of birth. Her caretaker, [REDACTED], was with her and told me that the patient cannot confirm her date of birth because she is "disabled". Patient's caretaker did tell me that the patient's mother had breast CA and her father had prostate CA.

The plan is to order a genetic testing battery to evaluate for disease risk as an efficient and effective way to analyze multiple genes and potential mutations that can be associated with particular conditions or individual health risks. In my expert opinion these tests would help in the management of this patient.

97. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications and representations were false because B.D. was not her "patient," she was not her treating physician and had not "evaluated" her, was not "managing" any of her medical conditions, and did not intend to use the results of the genetic tests to manage her conditions.

98. The false documentation also included requisition forms for Landmark Diagnostics for comprehensive genetic testing, which identified Dr. Mufti as the "ordering provider" and included her NPI, as well a certification signed by Dr. Mufti that the tests were medically

necessary, that Dr. Mufti was legally authorized to order the testing, and that B.D. “consented to have genetic testing performed.”

99. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications were false because Dr. Mufti had no provider-patient relationship with B.D. and was not authorized to order any testing for her, never examined B.D. to evaluate whether genetic testing would be medically necessary or provide any benefit to B.D., never intended to use the results of the tests to inform her treatment of B.D., and B.D., who was disabled, had not consented to, and was unable to consent to, the genetic testing.

100. Dr. Mufti also signed a letter of medical necessity that was to be provided to Medicare to facilitate payment of the claims for genetic testing for B.D. in which she requested “full coverage” for the testing and represented that B.D. was her “patient,” and that the results of the testing would be received by Dr. Mufti and used by her “in order to pursue care for my patient.”

101. These representations were false because, as Dr. Mufti knew, recklessly disregarded, or deliberately ignored Dr. Mufti had no provider-patient relationship with B.D., who was not her patient, and she did not receive and had no intention of receiving the results, or using them to pursue any care for B.D.

102. By approving B.D.’s consult for genetic testing, Dr. Mufti caused false and fraudulent claims for payment for genetic testing for B.D. to be presented to Medicare on or about June 16, 2019, knowing that the information contained in the claims was false, with deliberate ignorance of the truth or falsity of the information contained in the claims, or with reckless disregard of the truth or falsity of the information contained in the claims.

103. The false statements contained within the orders that Dr. Mufti signed were material, as Medicare would not and could not have paid these claims if it had known the truth.

104. As a result of Dr. Mufti’s fraudulent orders for genetic testing, Medicare in 2019 paid \$3,763.37 for false claims for medically unnecessary genetic testing for B.D.

Illustrations – Genetic Testing Order for Patient E.A.

105. Patient E.A. provides another example of Dr. Mufti’s role in ordering or causing the order of genetic testing for Medicare beneficiaries she never spoke with, much less examined.

106. On June 16, 2019, the same day Dr. Mufti approved CGx testing for patient B.D, Dr. Mufti ordered or caused to be ordered genetic testing for E.A., who at the time was a 57-year-old resident of Basile, Louisiana. Dr. Mufti’s signed SOAP note for E.A. reflects that Dr. Mufti called E.A. on that date, but was told that she had the “wrong number.”

107. Dr. Mufti nonetheless approved E.A. for genetic testing through the MSMD portal, which resulted in false documentation bearing Dr. Mufti’s electronic signature being created so that genetic testing could be performed by a clinical laboratory and billed to Medicare.

108. This false documentation included a certificate of medical consultation, signed by Dr. Mufti, representing that E.A. was her “patient,” that Dr. Mufti had “evaluated” her on June 16, 2019, that E.A. “would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition,” and stated that the “plan is to order a genetic testing battery to evaluate [E.A.] for disease risk,” which would help in the “management of this patient.”

Physician Encounter Note:

I called the contact phone number for direct patient call three times. On the third attempt a answered the phone and told me it was the "wrong number". According to the attached physician eval approval form, the patient's sister and grandmother had breast CA. Hence patient would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition.

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The plan is to order a genetic testing battery to evaluate for disease risk as an efficient and effective way to analyze multiple genes and potential mutations that can be associated with particular conditions or individual health risks. In my expert opinion these tests would help in the management of this patient.

109. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications and representations were false because E.A. was not her "patient," she was not E.A.'s treating physician, she had not examined or "evaluated" E.A., or even spoken to her, was not "managing" any of her medical conditions, and did not intend to use the results of the genetic tests to manage her conditions.

110. The false documentation also included requisition forms for Landmark Diagnostics for comprehensive genetic testing, which identified Dr. Mufti as the "ordering provider" and included her NPI, as well as her signed confirmations that the tests were medically necessary, that she was legally authorized to order the testing, and that E.A. "consented to have genetic testing performed."

111. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications were false because Dr. Mufti had no provider-patient relationship with E.A. and was not authorized to order any testing for her, never spoke to, examined, or evaluated E.A. to determine whether genetic testing would be medically necessary or provide any benefit to E.A., never intended to use the results of the tests to inform her treatment of E.A., and never spoke with E.A. regarding her consent to genetic testing.

112. Dr. Mufti also signed a letter of medical necessity that was to be provided to Medicare to facilitate payment of the claims for genetic testing for E.A. in which she requested “full coverage” for the testing and represented that E.A. was her “patient,” and that the results of the testing would be received by Dr. Mufti and used by her “in order to pursue care for my patient.”

113. By approving E.A.’s consult for genetic testing, Dr. Mufti caused false and fraudulent claims for payment for genetic testing for E.A. to be presented to Medicare on or about June 16, 2019, knowing that the information contained in the claims was false, with deliberate ignorance of the truth or falsity of the information contained in the claims, or with reckless disregard of the truth or falsity of the information contained in the claims.

114. These representations were false because, as Dr. Mufti knew, recklessly disregarded, or deliberately ignored, Dr. Mufti had no provider-patient relationship with E.A., who was not her patient, and she did not receive and had no intention of receiving the results, or using them to pursue any care for E.A.

115. The false statements contained within the orders that Dr. Mufti signed were material, as Medicare would not and could not have paid these claims if it had known the truth.

116. As a result of Dr. Mufti’s fraudulent orders for genetic testing, Medicare in 2019 paid \$4,980.78.00 for false claims for medically unnecessary genetic testing for E.A.

Illustrations – Genetic Testing Order for Patient A.S.

117. On June 17, 2019, the day after Dr. Mufti approved CGx testing for B.D. and E.A., Dr. Mufti ordered or caused to be ordered genetic testing for A.S., a then 82-year-old resident of New Iberia, Louisiana. Dr. Mufti’s signed SOAP note for A.S. reflects that Dr. Mufti attempted to call A.S. on that date, but that she was “unable to reach him.”

118. Dr. Mufti nonetheless approved A.S. for genetic testing through the MSMD portal, which resulted in false documentation bearing Dr. Mufti's electronic signature being created so that genetic testing could be performed by a clinical laboratory and billed to Medicare.

119. This false documentation included a certificate of medical consultation, signed by Dr. Mufti, representing that A.S. was her "patient," that Dr. Mufti had "evaluated" him on June 17, 2019, that A.S. "would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition," and stated that the "plan is to order a genetic testing battery to evaluate [A.S.] for disease risk," which would help in the "management of this patient." Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications and representations were false because A.S. was not her "patient," she was not his treating physician and had not "evaluated" him, was not "managing" any of his medical conditions, and did not intend to use the results of the genetic tests to manage her conditions.

Physician Encounter Note:

3 attempts made to call patient but was unable to reach him. According to form attached, his father had prostate CA and sister had brain CA. Hence patient would like to be better informed of any further risk(s) to themselves and/or family members by understanding their genetic composition.

The plan is to order a genetic testing battery to evaluate for disease risk as an efficient and effective way to analyze multiple genes and potential mutations that can be associated with particular conditions or individual health risks. In my expert opinion these tests would help in the management of this patient.

120. The false documentation also included requisition forms for Landmark Diagnostics, for comprehensive genetic testing, which identified Dr. Mufti as the "ordering provider" and included her NPI, as well as her signed confirmations that the tests were medically necessary, that she was legally authorized to order the testing, and that A.S. "consented to have genetic testing performed."

121. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these confirmations were false because the testing was not medically necessary, Dr. Mufti was not legally authorized to order the genetic testing, and A.S., whom she never spoke to, examined, or evaluated, had not consented to genetic testing.

122. By approving A.S.'s consult for genetic testing, Dr. Mufti caused the submission of false claims for reimbursement for patient A.S. and made or caused to be made false documents in A.S. medical records certifying that the genetic testing for A.S. was medically necessary. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the genetic testing were medically necessary were false because Dr. Mufti was not A.S.'s treating physician and the results of the tests were not used for diagnosis or treatment of any of A.S.'s medical conditions.

123. The false statements contained within the orders that Dr. Mufti signed were material, as Medicare would not and could not have paid these claims if it had known the truth.

124. As a result of Dr. Mufti's conduct, Medicare in 2019 paid \$3,763.37 to Landmark Diagnostics based on false claims for medically unnecessary genetic testing for A.S.

Illustrations – Genetic Testing Order for Patient M.F.

125. On July 24, 2019, Dr. Mufti ordered or caused to be ordered genetic testing for M.F., a then 71-year-old resident of Tidioute, Pennsylvania.

126. Despite not being M.F.'s treating provider, Dr. Mufti approved M.F. for a comprehensive battery of genetic testing through the MSMD portal, which resulted in false and fraudulent orders for genetic testing and supporting documentation bearing Dr. Mufti's electronic signature being created so that genetic testing for M.F. could be performed by a clinical laboratory and billed to Medicare.

127. This false documentation included, among other documents, a certificate of medical consultation, electronically signed by Dr. Mufti, representing that M.F. was her “patient,” that Dr. Mufti had “evaluated” her on July 24, 2019, and stated that the “plan is to order a genetic testing battery to evaluate [M.F.] for disease risk,” which would help in the “management of this patient.”

128. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications and representations were false because M.F. was not her “patient,” she was not her treating physician and had not “evaluated” her to determine whether genetic testing was medically necessary, she was not “managing” any of her medical conditions, and she did not intend to use the results of the genetic tests to manage any of M.F.’s conditions.

129. The false documentation also included requisition forms for Landmark Diagnostics for comprehensive genetic testing, which identified Dr. Mufti as the “ordering provider” and included her NPI, as well as her signed confirmations that the tests were medically necessary, that she was “legally authorized” to order the testing, and that the results of the testing would be used to “determine the patient’s medical management and treatment decision.”

130. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these confirmations were false because the testing was not medically necessary, Dr. Mufti was not legally authorized to order the genetic testing, and she did not use and had no intention of using the results of the testing to manage any of M.F.’s conditions or to inform any treatment decisions for M.F. Indeed, Dr. Mufti did not know, at the time she approved M.F.’s consult for genetic testing, whether M.F. would even be provided with the results of the genetic testing.

131. The false documentation also included a fraudulent “medical diagnosis” signed by Dr. Mufti recommending genetic testing in which Dr. Mufti represented that the testing would be used to inform future treatments and “preventative measures” for M.F., and “would help in the medical management of this patient.” In fact, as Dr. Mufti knew, M.F. was not her patient, and

she did not use, and had no intention of using the results of the genetic testing to manage M.F.'s clinical care or to inform any future treatments or preventative measures.

Medical Diagnosis

CGX

Plan of care: Recommended for this patient with a personal history and/or family history of cancer. This test identifies inherited gene mutations that reflect a predisposition to certain types of cancer. The results from this test will allow a comprehensive forecast of cancer risk to patient and future lineage. This genetic screening will also provide awareness, education and insight into potential pro-active treatments needed, early detection strategies and preventative measures for the patient.

Physician Notes: The plan is to order a genetic testing battery to evaluate for disease risk as an efficient and effective way to analyze multiple genes and potential mutations that can be associated with particular conditions or individual health risks. In my expert opinion these tests would help in the management of this patient.

Physician Name: Shayasta Mufti, MD, MD

NPI: [REDACTED]

Phone #: [REDACTED]

Physician Signature:



Mufti742

132. By approving M.F.'s consult for genetic testing, Dr. Mufti caused the submission of false claims for reimbursement for M.F. and made or caused to be made false documents in M.F. medical records certifying that the genetic testing for M.F. was medically necessary. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the genetic testing were medically necessary were false because Dr. Mufti was not M.F.'s treating physician and the results of the tests were not used for diagnosis or treatment of any of M.F.'s medical conditions.

133. The false statements contained within the orders that Dr. Mufti signed were material, as Medicare would not and could not have paid these claims if it had known the truth.

134. As a result of Dr. Mufti's conduct, Medicare in 2019 paid \$ \$7,569.45 to Landmark Diagnostics based on false claims for medically unnecessary genetic testing for M.F.

Illustrations – Genetic Testing Order for Patient J.H.

135. On September 9, 2019, Dr. Mufti ordered or caused to be ordered genetic testing for J.H., a then 72-year-old resident of Alexandria, Louisiana.

136. Despite not being J.H.'s treating provider, Dr. Mufti approved J.H. for a comprehensive battery of genetic testing through the MSMD portal, which resulted in false and fraudulent orders for genetic testing and supporting documentation bearing Dr. Mufti's electronic signature being created so that genetic testing for J.H. could be performed by a clinical laboratory and billed to Medicare.

137. This false documentation included a certificate of medical consultation, signed by Dr. Mufti, representing that J.H. was her "patient," that Dr. Mufti had "evaluated" him on September 9, 2019, and stated that the "plan is to order a genetic testing battery to evaluate [J.H.] for disease risk," which would help in the "management of this patient."

138. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these certifications and representations were false because J.H. was not her "patient," she was not his treating physician and had not "evaluated" him, was not "managing" any of his medical conditions, and did not intend to use the results of the genetic tests to manage any of his conditions.

139. The false documentation also included requisition forms for Principle Labs, LLC ("Principle Labs"), a diagnostic laboratory in Bethlehem, Pennsylvania, for comprehensive genetic testing, which identified Dr. Mufti as the "ordering provider" and included her NPI, as well as her signed confirmations that the tests were medically necessary, that she was "legally authorized" to order the testing, and that the results of the testing would be used to "determine the patient's medical management and treatment decision."

140. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that these confirmations were false because the testing was not medically necessary, Dr. Mufti was not legally authorized to order the genetic testing, and she did not use and had no intention of using the results of the testing to manage any of J.H.’s conditions or to inform any treatment decisions for J.H. Indeed, Dr. Mufti did not know, at the time she approved J.H.’s consult for genetic testing, whether J.H. would even be provided with the results of the genetic testing.

141. The false documentation also included a fraudulent “medical diagnosis” signed by Dr. Mufti recommending genetic testing in which Dr. Mufti represented that the testing would be used to inform future treatments and “preventative measures” for J.H., and “would help in the medical management of this patient.” In fact, as Dr. Mufti knew, J.H. was not her patient, and she did not use, and had no intention of using the results of the genetic testing to manage J.H.’s clinical care or to inform any future treatments or preventative measures for J.H.

142. By approving J.H.’s consult for genetic testing, Dr. Mufti caused the submission of false claims for reimbursement for J.H. and made or caused to be made false documents in J.H.’s medical records certifying that the genetic testing for J.H. was medically necessary. Dr. Mufti knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the genetic testing were medically necessary were false because Dr. Mufti was not J.H.’s treating physician and the results of the tests were not used for diagnosis or treatment of any of J.H.’s medical conditions.

143. The false statements contained within the orders that Dr. Mufti signed were material, as Medicare would not and could not have paid these claims if it had known the truth.

144. As a result of Dr. Mufti’s conduct, Medicare in 2019 paid \$7,194.38 to Principle Labs based on false claims for medically unnecessary genetic testing for J.H.

COUNT I
(Violation of False Claims Act)
(31 U.S.C. § 3729(a)(1)(A))

145. The United States repeats and realleges the allegations set out above as if fully set forth herein.

146. Defendant violated the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), by causing to be presented to Medicare false and fraudulent claims for payment for genetic cancer tests.

147. Defendant caused such false and fraudulent claims for payment for genetic cancer tests to be presented to Medicare knowingly, or with deliberate ignorance of—or reckless disregard to—the truth or falsity of the information contained in the false and fraudulent claims.

148. The false statements contained within the orders that Defendant signed were material, as Medicare would not and/or could not have paid these claims if it had known the truth.

149. The United States paid the materially false and fraudulent claims because of Defendant's acts, and incurred damages as a result.

150. Pursuant to 31 U.S.C. § 3729(a), Defendant is liable to the United States Government for a civil penalty for each violation of the False Claims Act committed by Defendant.

151. Pursuant to 31 U.S.C. § 3729(a), Defendant is liable to the United States for three times the amounts of all damages sustained by the United States because of Defendant's conduct.

COUNT II
(Violation of the False Claims Act)
(31 U.S.C. § 3729(a)(1)(B))

152. The United States repeats and realleges the allegations set out above as if fully set forth here.

153. Defendant violated the False Claims Act, 31 U.S.C. § 3729(a)(1)(B), by knowingly making, using, or causing to be made or used, false records or statements that were material to

false or fraudulent claims for payment to Medicare, or by acting with deliberate ignorance of—or reckless disregard to—the truth or falsity of such records or statements.

154. The false statements contained within the orders that Defendant signed were material, as Medicare would not and could not have paid these claims if it had known the truth.

155. The United States paid the materially false and/or fraudulent claims because of Defendant's acts, and incurred damages as a result.

156. Pursuant to 31 U.S.C. § 3729(a), Defendant is liable to the United States Government for a civil penalty for each violation of the False Claims Act committed by Defendant.

157. Pursuant to 31 U.S.C. § 3729(a), Defendant is liable to the United States for three times the amounts of all damages sustained by the United States because of Defendant's conduct.

COUNT III
(Negligence)

158. The United States repeats and realleges the allegations contained in this Complaint set out above as if fully set forth here.

159. This is a claim for the recovery of damages to the United States Medicare program caused by Defendant's negligence.

160. Defendant, owing a duty of care to the United States as a licensed provider under the Medicare program who promised to use due care in submitting and causing the submission of claims to Medicare, negligently breached that duty, causing damages to the United States in the form and amount of payments made by Medicare upon claims based on orders or caused to be placed by Defendant for genetic cancer testing for patients that Defendant was not treating. Defendant is liable to the United States for those damages.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendant as follows:

I. On the First and Second Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Third Counts, for the damages caused to the United States as a result of Defendant's negligence, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

III. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States demands a trial by jury in this case.

Respectfully submitted,

DYLAN J. STEINBERG
Acting United States Attorney

/s/ Jacob Laksin
Jacob Laksin
Assistant U.S. Attorney

Dated: June 23, 2025

