IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
ex rel., JONATHAN D'CUNHA, M.D.,)	Civil Action No. 19-495
)	
Plaintiff,)	
)	District Judge Cathy Bissoon
V.)	
)	
DR. JAMES D. LUKETICH,)	
UNIVERSITY OF PITTSBURGH)	
MEDICAL CENTER, AND)	JURY TRIAL DEMANDED
UNIVERSITY OF PITTSBURGH)	
PHYSICIANS,)	
)	
Defendants.)	

THE UNITED STATES OF AMERICA'S COMPLAINT IN PARTIAL INTERVENTION

NOW COMES the United States of America (the "Government" or the "United States"), by and through its attorney, Stephen R. Kaufman, Acting United States Attorney for the Western District of Pennsylvania, and brings this Complaint in Partial Intervention against Defendants the University of Pittsburgh Medical Center ("UPMC"), University of Pittsburgh Physicians ("UPP"), and James Luketich, M.D. ("Luketich) (collectively, "Defendants"), alleging as follows:

I. Summary of Allegations

1. This is a civil fraud action brought by the United States against Defendants under the False Claims Act, 31 U.S.C. § 3729-3733, to recover treble damages sustained by, and civil penalties owed to, the United States, resulting from false and/or fraudulent claims for reimbursement submitted by UPMC, UPP, and Luketich, and/or their agents and employees, to Medicare, Medicaid, TRICARE, and/or the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") (collectively, "Government Health Benefit Programs").

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2. As more fully alleged below, this civil fraud action concerns longstanding, knowing, and egregious violations of the public trust and patient rights; of the applicable medical standard of care; of the federal statutes, regulations, and guidance governing surgical practice at teaching hospitals; and of the FCA, by Pittsburgh-area healthcare providers that advertise themselves as global leaders in patient-centered care.

3. For years, and since at least 2015 (the "Claims Period"), UPMC – which promotes itself as one of the premier healthcare providers in the world, and which reaps tens of billions of dollars in revenue each year – has knowingly allowed Luketich – the longtime chairman of UPMC's Department of Cardiothoracic Surgery (the "CT Department") and one of UPMC's highest-paid employees – to book and perform three surgeries at the same time, to miss the surgical time outs at the outset of those procedures, to go back-and-forth between operating rooms and even hospital facilities while his surgical patients remain under general anesthesia, to leave those anesthetized patients for hours at a time while he attends to other matters, to falsely attest that he was with his patients throughout the entirety of their surgical procedures or during all "key and critical" portions of those procedures, and to unlawfully bill Government Health Benefit Programs for those procedures, all in order to increase surgical volume, maximize UPMC and UPP's revenue, and/or appease Luketich.

4. These practices – which are well-known to many current and former UPMC executives, surgeons, anesthesiologists, nurses, and staff, but *not to* Luketich's patients – violate: the federal statutes and regulations that govern the Medicare, Medicaid, CHAMPVA, and TRICARE programs, and that apply to teaching hospitals (like UPMC) and teaching physicians (like Luketich); departmental and agency guidance; and UPMC policy.

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5. But these are not merely technical violations of billing requirements or internal policies. To the contrary, Luketich's surgical practices also defy the standard of care, abuse patients' trust, inflate anesthesia time, increase the risk of complications to patients, and – on at least several occasions during the Claims Period – have resulted in serious harm to patients. Indeed, and as more fully detailed below, some of Luketich's patients were forced to endure additional surgical procedures and/or extended hospital stays as a result of his unlawful conduct. Numerous patients developed painful pressure ulcers. A few were diagnosed with compartment syndrome. And at least two had to undergo amputations.

6. Nonetheless, UPMC has persistently ignored or minimized complaints by employees and staff regarding Luketich, his hyper-busy schedule, his refusal to delegate surgeries and surgical tasks to other attending physicians or abide by the applicable statutes, regulations, policies, and standard of care, and the resultant effects on patient outcomes; protected him from meaningful sanction; refused to curtail his surgical practice; and continued to allow Luketich to skirt the rules and endanger his patients.

7. More than that, UPMC has repeatedly and publicly *promoted* Luketich and his practice during the Claims Period. Indeed, despite Luketich's unlawful conduct, the complaints and poor outcomes associated with that conduct, and UPMC leadership's knowledge of the same, UPMC has regularly showcased Luketich to the public, advertising him (and the CT Department generally) as global leaders in minimally invasive surgical procedures and other innovative and life-saving techniques, and holding him out as a reason for patients to "Choose UPMC" when faced with serious health problems.

8. For example, in a television commercial that aired in 2019, and that is still available on YouTube (*see <u>https://www.youtube.com/watch?v=RupyyhSB1a0</u> (last visited August 31,*

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2021)), UPMC promotes Luketich as an innovative surgeon who routinely performs dramatic, lastditch procedures on patients who are otherwise "hopeless." In the commercial, Luketich boasts that on a "weekly" basis, "someone is seen in the clinic that has been turned down elsewhere, that had been told, 'Surgery's not going to help, you're never going to eat again, or you're never going to breathe again without oxygen and sitting in a wheelchair,' but at UPMC ... [we're] helping a patient who's been told there is no hope." At one point during the commercial, the camera zooms in on Luketich's embroidered white-coat, to clearly display his name and title. And at the end of the commercial, Luketich says, "I chose UPMC, because the future is here," as the following graphic appears:



9. Contrary to the picture painted in UPMC's marketing materials, Defendants have – throughout the Claims Period – regularly sacrificed patient health in order to increase surgical volume in the CT Department, to ensure that Luketich – and only Luketich – performs certain portions of surgical procedures, and to maximize profit.

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10. As a result of these longstanding practices, UPMC, UPP, and Luketich have not only jeopardized patient health, they have also submitted hundreds of materially false claims for reimbursement to Medicare, Medicaid, and other Government Health Benefit Programs, and caused millions of dollars of damage to the United States over the course of the Claims Period.

II. Jurisdiction and Venue

This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §
 1331, 28 U.S.C. § 1345, 31 U.S.C. § 3730(a), and 31 U.S.C. § 3732.

12. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process, and because the Defendants have minimum contacts with the United States, and are residents of, headquartered in, and/or transact business in, the Western District of Pennsylvania.

Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because
 Defendants reside, are headquartered in, and/or transact business in, and the acts proscribed by 31
 U.S.C. § 3729 were committed in, the Western District of Pennsylvania.

III. The Parties

14. Relator Jonathan D'Cunha, M.D., Ph.D. ("Relator") is a cardiothoracic surgeon and the current chair of cardiothoracic surgery at the Mayo Clinic in Phoenix, Arizona. From 2012 to 2019, Relator was employed by UPMC, contracted with UPP to provide physician services at UPMC facilities, and resided in this District. During his tenure at UPMC, Relator served as UPMC's Vice Chair of Research and Education in the Department of Cardiothoracic Surgery, Surgical Director of Lung Transplantation, and Division Head of Lung Transplantation/Lung Failure, and worked closely with, and regularly observed, Luketich, as well as the other physicians and staff comprising or associated with the CT Department.

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15. UPMC is a nonprofit corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business in Pittsburgh, Allegheny County, Pennsylvania. UPMC is a teaching hospital, as that term is defined under 42 C.F.R. § 415.152, and maintains one of the largest medical residency programs in the country, which annually includes more than 20 cardiothoracic surgery medical residents. During the Claims Period, UPMC reported total operating revenues ranging from \$12 billion for Calendar Year ("CY") 2015 to \$23 billion for CY 2020.

16. UPP is a nonprofit corporation organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business in Pittsburgh, Allegheny County, Pennsylvania. UPP's sole member is UPMC. UPP functions as a multi-specialty physician practice group that provides physician services to patients, including surgeries performed by Luketich and other cardiothoracic surgeons employed by and/or affiliated with UPMC, and anesthesia services provided to Luketich's patients by anesthesiologists employed by and/or affiliated with UPMC.

17. Luketich is the longtime Chair of UPMC's CT Department, as well as the Chief of UPMC's Division of Thoracic and Foregut Surgery, the Director of Thoracic Surgical Oncology at UPMC, and the Henry T. Bahnson Professor of Cardiothoracic Surgery at UPMC. Luketich also contracts with UPP to provide physician services, and bills Medicare, Medicaid, other Government Health Benefit Programs, and private insurers, for his services through UPP. Luketich is one of UPMC's highest-paid employees – UPMC paid him more than \$2.4 million annually from 2017-2019 – and is a resident of this District.

IV. The Legal Framework

A. The False Claims Act

18. The FCA prohibits any person from knowingly making, or causing to be made, a false or fraudulent claim for payment to the United States. 31 U.S.C. § 3729(a)(1)(A). The FCA

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also prohibits knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B). In addition, the FCA prohibits knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States. 31 U.S.C. § 3729(a)(1)(G).

19. A false or fraudulent claim under the FCA may take many forms, "the most common of which is a claim for payment for goods and services not provided or provided in violation of contract terms, specification, statute or regulation." False Clams Amendment Act of 1986, S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274.

20. The misrepresentation must be "material," which the FCA defines 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. The FCA defines "knowingly" to include actual knowledge, reckless disregard, and deliberate ignorance. 31 U.S.C. § 3729(b)(1)(A). No specific intent to defraud need be shown.
31 U.S.C. § 3729(b)(1)(B).

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 healthcare services. The Department of Health and Human Services ("HHS") is responsible for administering and supervising the Medicare program. The Center for Medicare and Medicaid Services ("CMS") is a component of HHS and is directly responsible for administering the Medicare program.

23. An individual may be entitled to Medicare coverage based on his or her age, disability, or affliction with end-stage renal disease. 42 U.S.C. § 426.

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24. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."

25. The Medicare regulations define a "provider" to include "a hospital . . . that has in effect an agreement to participate in Medicare." 42 C.F.R. § 400.202.

26. There are four Parts to the Medicare Program: Part A authorizes payment for institutional care, including inpatient hospital care, skilled nursing facility care, and home health care, see 42 U.S.C. §§ 1395c-1395i-4; Part B primarily covers outpatient care, including physician services and ancillary services, see 42 U.S.C. § 1395k; Part C is the Medicare Advantage Program, which provides Medicare benefits to certain Medicare beneficiaries through private health insurers, called Medicare Advantage Organizations ("MAOs"), *see* 42 U.S.C. § 1395w-21, *et seq.*; and Part D provides prescription drug coverage, see 42 U.S.C. § 1395w-101, et seq.; 42 C.F.R. § 423.1, *et seq.*

27. Since November 2006, CMS has contracted with Medicare Administrative Contractors ("MACs") to assist in the administration of Medicare Parts A and B. *See* Fed. Reg. 67960, 68181 (Nov. 2006). MACs generally act as CMS's agents in reviewing and paying Part A and Part B claims submitted by healthcare providers and perform administrative functions on a regional level. See 42 C.F.R. § 421.5(b); *see also* 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104.

28. Under the Medicare program, CMS (through MACs) makes payments prospectively for hospital inpatient services, through periodic payments and the cost-report reconciliation process described below, and retrospectively for hospital outpatient services, after the services are rendered.

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29. Upon discharge of Medicare beneficiaries from a hospital, the hospital submits Medicare Part A claims for reimbursement for inpatient items and services delivered to those beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Inpatient services are paid using the Inpatient Prospective Payment System. In addition, designated hospital outpatient items and services are paid under the Outpatient Prospective Payment System. Hospitals submit claims for Medicare reimbursement using the electronic claim form known as the 837I or its paper equivalent, Form CMS-1450 (also known as the UB-04). The claim form instructions, found in Chapter 25, section 75 of the Claims Processing Manual, set forth the Medicare requirements for use of the various codes in completing the form.

30. When physicians provide patient care services in a hospital setting, whether to hospital inpatients or outpatients, they (or an entity to which they have assigned billing rights) may bill Medicare for their "professional" services, which include performing procedures and interpreting test results, using a CMS Form 1500. The hospital may submit a separate claim to Medicare for the "technical" or "facility" component of the services rendered, as described in the preceding paragraph, under which the hospital is reimbursed for furnishing, among other things, equipment and non-physician staff.

31. Providers must be enrolled in Medicare in order to be reimbursed under Medicare Part A or B. *See* 42 C.F.R. § 424.505. To enroll in Medicare, institutional providers such as hospitals periodically must complete a Medicare Enrollment Application (often called a Form CMS-855A). In completing the Medicare Enrollment Application, an institutional provider certifies:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by

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Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and Stark Law), and on the provider's compliance with all applicable conditions of participation in Medicare.

The Medicare Enrollment Application also summarizes the FCA in a separate section that explains the penalties for falsifying information in the Application to "gain or maintain enrollment in the Medicare program."

32. As part of the above certification in the Medicare Enrollment Application, the physician and hospital further agree to: "not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare," and to "not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

33. Medicare enrollment regulations further require providers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

34. Medicare only pays for services that are reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member. 42U.S.C. §1395y(a)(1)(A).

35. As a prerequisite to Medicare payment under Medicare Part A, CMS also requires hospitals to submit annually a form CMS-2552, commonly known as a hospital cost report. A cost report is the final claim that a provider submits to a MAC for items and services rendered to Medicare beneficiaries during the year covered by the report.

36. After the end of each of a hospital's fiscal years, the hospital files its hospital cost report with the MAC, stating the amount of Part A reimbursement the provider believes it is due for the year, or the amount of excess reimbursement it has received through interim payments during the year that it owes back to Medicare. *See* 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. *See*

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also 42 C.F.R. § 405.1801(b)(1). Medicare relies upon the hospital cost report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare. *See* 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1).

37. Medicare Part A payments for Social Security Act section 1886(d) hospital services, *see* 42 U.S.C. § 1395ww, are determined under a prospective payment system using the claims submitted by the provider for particular patient discharges (specifically listed on UB-92s and UB-04s) during the course of the fiscal year. On the hospital cost report, the prospective payments for services are added to any other Medicare Part A add-on payments due to the provider. This total determines Medicare's liability for services rendered to Medicare Part A beneficiaries during the course of a fiscal year. From this sum, the payments made to the provider during the year are subtracted to determine the amount due the Medicare Part A program or the amount due the provider.

38. Every hospital cost report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

39. That chief administrator or designee is required to certify that the hospital cost report "is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted ... and that the services identified in this cost report were provided in compliance with such laws and regulations."

40. In addition, the hospital cost report certification page contains a notice that: "Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law."

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41. Thus, a provider must certify: (1) that the filed hospital cost report is truthful, *i.e.*, that the cost information contained in the report is true and accurate; (2) that it is correct, *i.e.*, that the provider is entitled to reimbursement for the reported costs in accordance with applicable instructions; (3) that it is complete, *i.e.*, that the hospital cost report is based upon all information known to the provider; and (4) that the services provided in the cost report were billed in compliance with applicable laws and regulations.

42. A hospital is required to disclose all known errors and omissions in its claims for Medicare Part A reimbursement (including its cost reports) to its MAC.

43. Medicare, through its MACs, has the right to audit a provider hospital's cost reports and financial representations to ensure their accuracy and preserve the integrity of the Medicare Trust Funds. This right includes the right to make retroactive adjustments to hospital cost reports previously submitted by a provider if any overpayments have been made. *See* 42 C.F.R. § 413.64(f).

44. Under Medicare Part B, a physician may submit claims for reimbursement using either a hard copy or electronic CMS 1500 form. In doing so, the physician must certify that he/she is knowledge of Medicare's requirements, and that the individual claim complies with applicable laws and regulations.

45. Under Medicare Part C, the Government pays each MAO a fixed monthly payment for each Medicare beneficiary enrolled in the MAO's plan. The Government adjusts these payments for various risk factors that affect expected healthcare expenditures, including the health status of each enrollee. The adjustments are intended to ensure that MAOs are paid more for those enrollees expected to incur higher healthcare costs and less for healthier enrollees expected to incur lower costs.

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46. To obtain payments based on adjustment for health status, MAOs submit diagnosis codes to the Government for the beneficiaries in their Medicare Advantage plans. These diagnosis codes are based on the beneficiaries' medical encounters (e.g., office visits, surgical procedures, and hospital stays). Using these diagnosis codes, the Government creates a risk score for each beneficiary. The beneficiary's risk score is then used to calculate monthly payments to the MAOs for that beneficiary for the following year. In general, the more numerous and severe the beneficiary's conditions, the higher his/her risk score will be, and the greater the risk-adjusted payments to the MAO will be during the next year.

47. Many of Defendants' patients are enrolled in Medicare Advantage plans under Medicare Part C.

48. UPMC currently has four, fully-owned subsidiaries (UPMC Health Coverage, Inc., UPMC Health Network, Inc., UPMC Health Plan, Inc., and UPMC For You, Inc.) that operate as MAOs.

49. Through those fully-owned subsidiaries, UPMC offers at least one Medicare Advantage plan – UPMC for Life – to eligible individuals.

50. Many of Defendants' patients – including dozens of Luketich's surgical patients during the Claims Period – are or were UPMC for Life beneficiaries.

C. Medicaid

51. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The Government's involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program.

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52. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation ("FFP"). 42 U.S.C. § 1396, *et seq.*

53. Each state's Medicaid program must cover hospital services. 42 U.S.C. § 1396a(10)(A), 42 U.S.C. § 1396d(a)(1)-(2).

54. In many states, provider hospitals participating in the Medicaid program file annual cost reports with the state's Medicaid agency, or its intermediary, in a protocol similar to that governing the submission of Medicare cost reports.

55. In some states, provider hospitals participating in the Medicaid program file a copy of their Medicare cost report with the Medicaid program which is then used by Medicaid or its intermediaries to calculate Medicaid reimbursement. In other states, provider hospitals file a separate Medicaid cost report.

56. Providers incorporate the same type of financial data in their Medicaid cost reports as contained in their Medicare cost reports, and include data concerning the number of Medicaid patient days at a given facility.

57. Typically, each state requiring the submission of a Medicaid cost report also requires an authorized agent of the provider to expressly certify that the information and data on the cost report is true and correct.

58. Individual Medicaid programs use the Medicaid patient data in the cost report to determine the reimbursement to which the facility is entitled. The facility receives a proportion of its costs equal to the proportion of Medicaid patients in the facility.

59. Where a provider submits the Medicare cost report with false or incorrect data or information to Medicaid, this necessarily causes the submission of false or incorrect data or

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information to the state Medicaid program, and the false certification on the Medicare cost report necessarily causes a false certification to Medicaid as well.

60. Where a provider submits a Medicaid cost report containing the same false or incorrect information from the Medicare cost report, false statements and false claims for reimbursement are made to Medicaid.

61. The state directly reimburses physicians for services rendered, with the state obtaining the federal share of the payment from accounts, which draw on funds of the United States Treasury. 42 C.F.R. §§ 430.0-430.30. The federal share of each state's Medicaid program varies state by state.

62. The Commonwealth of Pennsylvania participates in the Medicaid Program, through its Department of Public Welfare ("DPW"), the state agency responsible for administering the Medicaid Program.

63. At all times relevant to the complaint, the United States provided federal funds to Pennsylvania and its DPW through the Medicaid program, pursuant to Title XIX of the Social Security Act 42 U.S.C. §§ 1396 *et seq*. Enrolled providers of medical services to Medicaid recipients, including each of the Defendants, are eligible for reimbursement for covered medical services under the provisions of Title XIX of the 1995 Amendments to the Federal Social Security Act. By becoming a participating provider in Medicaid, enrolled providers, including each of the Defendants, agree to abide by the rules, regulations, policies, and procedures governing reimbursement, and to keep and allow access to records and information by Medicaid. In order to receive Medicaid funds, enrolled providers, together with authorized agents, employees and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures promulgated by DPW.

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64. Applicable provisions of 42 CFR, Chapter 4, Subpart D, and other applicable Federal statutes, provide for payments for physician services and providers and facilities providing physician services, including Defendants, as long as such services were medically indicated, necessary to the health of the patient, and certified as required by Medicare and Intermediary rules. Like Medicare, a "claim" under Medicaid is only reimbursable if it is "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. § 402.3

D. TRICARE and CHAMPVA

65. In 1967, the Department of Defense created the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), which is a federally funded medical program created by Congress. 10 U.S.C. § 1071. CHAMPUS beneficiaries include active military personnel, retired personnel, and dependents of both active and retired personnel. *Id.*

66. In 1995, the Department of Defense established TRICARE, a managed healthcare program, which operates as a supplement to CHAMPUS. *See* 32 C.F.R. §§ 199.4, 199.17(a). Since the establishment of TRICARE in 1995, both programs are frequently referred to collectively as TRICARE/CHAMPUS, or just "TRICARE." The purpose of the TRICARE program is to improve healthcare services to beneficiaries by creating "managed care support contracts that include special arrangements with civilian sector health care providers." 32 C.F.R. § 199.17(a)(1). The TRICARE Management Activity ("TMA") oversees this program.

67. TRICARE health services are provided through both "Network Providers" and "Non-Network Providers." Providers who are Medicare-certified providers are also considered TRICARE-authorized providers.

68. Network Providers include hospitals, other authorized medical facilities, doctors and healthcare professionals, all of whom enter into an agreement with the region's managed care

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contractor, and provide services for an agreed reimbursement rate. 32 C.F.R. § 199.14(a). Non-Network Participating Providers include hospitals, other authorized medical facilities, and doctors and healthcare professionals who do not enter an agreement with the region's managed care provider, and are reimbursed at rates established by TRICARE regulations. *Id.*

69. Just as with Medicare and Medicaid, TRICARE providers have an obligation to provide services and supplies at only the appropriate level and "only when and to the extent medically necessary." 32 C.F.R. § 199.6(a)(5).

70. TRICARE's governing regulations, like Medicare's and Medicaid's requirements also are based upon "medical necessity." TRICARE's governing regulations require that services provided be "furnished at the appropriate level and only when and to the extent medically necessary," and such care must "meet[] professionally recognized standards of health care [and be] supported by adequate medical documentation . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." 32 C.F.R. § 199.6(a)(5). In this respect, similar to Medicare and Medicaid, services provided at a level higher than the medically necessary are improper and violations of TRICARE. *Id.*

71. CHAMPVA is a comprehensive healthcare program that is administered by the Department of Veterans affairs. CHAMPVA is open to former members of the uniformed services who are not eligible for TRICARE and who are or were rated permanently and totally disabled due to a service-connected disability or condition, and their families.

E. Teaching Hospitals

72. As alleged above, UPMC is a teaching hospital within the meaning of 42 C.F.R. § 415.152. As such, UPMC receives direct graduate medical education ("GME") funds from the Government to subsidize the cost of its medical residency program, including payments for resident salaries and to cover the cost of the training that teaching physicians provide to residents,

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and must abide by additional conditions of payment to receive reimbursement from Medicare, Medicaid, or other Government Health Benefit Programs.

73. A teaching physician is defined as a physician, other than a resident, who involves residents in the care of his or her patients. *See* 42 C.F.R. § 415.152; CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, §100. A resident is an individual who participates in an approved graduate medical education program. *Id.*

74. To receive additional payment from a Government Health Benefit Program for physician services rendered in a surgical procedure performed at a teaching hospital, the claimant must certify that the procedure met certain criteria that are expressly labeled as "conditions of payment." 42 C.F.R. § 415.170. Those conditions include that the services: (a) are personally furnished by a physician who is not a resident; or (b) are furnished by a resident in the presence of a teaching physician. Id.

75. If a resident participates in the surgical procedure, the teaching physician may only submit a physician service claim to Medicare if the teaching physician was physically present for the "key portions" or "critical portions" of the surgical procedure. 42 C.F.R. § 415.172(a)(1); CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, § 100.1 (Payment for Physician Services in Teaching Settings).

76. In addition, in the case of surgery or other complex procedures – such as the procedures performed by Luketich that are at issue in this Complaint – the teaching physician must be present for all "critical portions" of the procedure *and* "immediately available" during the entire service or procedure. 42 C.F.R. § 415.172(a)(1); CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, § 100.1.2 (Surgical Procedures).

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77. These requirements are central to the Government's bargain with teaching hospitals, and are not minor and insubstantial, as they help ensure that residents' work is adequately supervised, and that patients receive appropriate care.

78. CMS defines "critical portion" to be the portion of the procedure the teaching physician determines to be critical. CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, § 100 (Teaching Physician Services, Definitions).

79. The "time out" is a "surgical pause" preceding incision, during which all operatingroom activity briefly ceases, and the surgical team completes a verbal checklist (confirming, among other things, the patient's identity, the incision site, and the procedure to be performed), and discusses the key and critical components of the procedure.

80. The "time out" is meant to help prevent so-called "sentinel" events, where the patient suffers severe and unanticipated surgical complications. According to the American College of Surgeons, it is the primary surgeon's responsibility to lead the surgical team through the "time out." Likewise, the World Health Organization's Joint Commission has repeatedly stated that "all [surgical] team members be actively involved in the [time out] process."

81. According to UPMC policy, the "time out" is a key and critical portion of every surgical procedure. *See* UPMC Policy and Procedure HS-0R0013, § IV(5).

82. On its website, UPMC acknowledges the significance of the "time out" requirement, and specifically claims that – in "do[ing] everything possible to prevent surgical complications" – it requires all surgeons to participate in a "time out" before the operation begins, and that, during said "time out," "[e]veryone on our surgical team suspends other duties to actively confirm or re-confirm important information, such as [the patient's] identity, procedure consent, procedure site, and other safety precautions based on [the patient's] medical history." (*See*

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https://www.upmc.com/about/why-upmc/quality/patient-safety/avoiding-injuries/surgical-safety (last visited August 31, 2021).)

83. In addition, the teaching physician "must personally document in the medical record that he/she was physically present during the critical or key portion(s)" of the procedures. 42 C.F.R. § 415.172.

84. As alleged above, while the teaching physician must be physically present for all key and critical portions of the surgical procedure, CMS also requires that, if a teaching physician cannot be physically present during the *non*-critical portions of the surgery, the physician must be "immediately available" to return to the procedure; that is, "he/she cannot be performing another procedure." CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, § 100.1.2 (Surgical Procedures), at A.

85. UPMC shares CMS's understanding of the requirement that a teaching physician be "immediately available," defining that term to mean "located on the hospital campus, reachable through the standard paging system, and able to return immediately to the operating room or procedure area if called (i.e., **not performing another procedure**)." *See* UPMC Policy and Procedure, HS-0R0013, § IV(6) (emphasis added).

86. The teaching physician may only leave the first surgical procedure and/or commence the second procedure when the key or critical portion(s) of the first procedure is complete. Surgical residents or fellows may finish the non-critical portion(s). Surgeries in compliance with this rule are often called overlapping surgeries.

87. Although a teaching physician may engage in two overlapping surgical procedures, the critical portions of the procedures cannot occur at the same time. CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, §100.1.2 (Surgical Procedures), at A.2.

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When a teaching physician becomes involved in a second procedure, he or she must assign another qualified physician to be immediately available. CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, §100.1.2 (Surgical Procedures), at A.

88. CMS will not pay for surgeries where the key or critical portions of each surgery take place at the same time, also known as concurrent surgery. UPMC policies and procedures prohibit concurrent surgery except in very rare emergent cases and then only for as short a time as possible pending arrival of the immediately available or on-call surgeon. *See* UPMC Policy and Procedure, HS-0R0013, § IV(4). Likewise, the American College of Surgeons differentiates between overlapping and concurrent surgeries, and expressly notes in its guidelines that CMS will not pay physicians for concurrent surgeries.

89. Although a teaching physician may bill for two overlapping surgeries that comply with the above-described rules, in the case of three overlapping surgeries, the role of the teaching physician is always classified as "supervisory service" to the hospital and is not billed as a physician service to a patient or payable under the physician fee schedule. CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, § 100.1.2. (Surgical Procedures), at A.2.

90. A surgeon may bill for procedures as a co-surgeon only in specified circumstances. When a teaching physician submits a claim for payment as a co-surgeon at a teaching hospital, the physician must certify that no qualified resident was available. 42 C.F.R. §415.190; CMS Medicare Claims Processing Manual, Rev. 4173 (11-30-2018), Chapter 12, §100.1.7 (Assistants at Surgery in Teaching Hospitals).

91. With regard to anesthesia, Medicare reimburses anesthesiologists for the period of time during which they are "present with the patient." Anesthesia time is a "continuous" time block and the actual amount of time spent with the patient is "reported on the claim for payment."

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For computing payment, anesthesia time is divided into 15-minute increments and rounded up to one decimal place.

92. Accurate documentation of medical treatment pertaining to surgeries is a condition of Medicare reimbursement, and CMS policy expressly limits payment to services for which there is documentation demonstrating the appropriate level of services required by the patient. *See* Medicare Carriers Manual, Part 3 CMS Pub. 14-3 (Rev. 1780); 42 C.F.R. § 415.172 *et seq*.

V. DEFENDANTS' FRAUDULENT CONDUCT

A. Luketich's Concurrent Surgery Practice

93. Despite his administrative responsibilities and chair position, Luketich maintains an inordinately busy surgical practice. He is – and has been for years – one of UPMC and UPP's most active surgeons, performing and assisting with hundreds, and sometimes thousands, of surgical procedures per year.

94. Luketich is also one of UPMC and UPP's highest sources of revenue. The surgeries he performs, participates in, or oversees as Chair of the CT Department, generate tens of millions of dollars of revenue for UPMC and UPP each year. That revenue includes not only the physician fees, anesthesia billings, and hospital costs directly associated with the surgical procedure(s), but also – quite often –billings from pre- and post-operative clinical visits, follow-up or subsequent surgical procedures, pre- and post-operative admissions to and stays at UPMC hospitals, post-operative rehabilitation and treatment, and referrals to other UPMC physicians, including pulmonologists and gastroenterologists.

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95. On information and belief, Luketich also generates additional, indirect revenue for UPMC and/or UPP through his connection to and work for the University of Pittsburgh Medical School, his oversight and management of the cardiothoracic residency and fellowship programs, his involvement in and/or direction of UPMC's lung transplant program, his surgical and academic reputation, and UPMC's promotion of the same.

96. Many of Luketich's surgical patients are elderly, frail, and/or very ill. They include the "hopeless" patients – as UPMC put it in its 2019 advertisement promoting Luketich's surgical practice – who suffer from chronic illness or metastic cancer, and/or have extensive surgical histories, and choose UPMC and Luketich when other physicians and healthcare providers have turned them down.

97. Many of Luketich's surgical patients are admitted to UPMC hospitals, undergo follow-up and/or subsequent surgical procedures at UPMC, and/or are referred to UPMC and UPP physicians for their post-operative treatment and care, and accordingly generate significant downstream revenue for UPMC and UPP, beyond Luketich's initial surgical procedures. And at least some of those post-operative admissions, surgical procedures, and doctor visits would not have been undertaken or indicated but for the unlawful practices described herein.

98. Many of Luketich's surgical patients are insured by a Government Health BenefitProgram.

99. As alleged further below, Luketich's "concurrent" surgery practices violate the statutes and regulations governing surgical practice at teaching hospitals, and the conditions of payment for the relevant Government Health Benefit Programs, in at least three ways, and has resulted in the submission of materially false claims for payment to the United States.

i. Luketich Regularly Plans to Perform, Performs, and Bills for, Three Complex Surgical Procedures that Overlap in Time, in Violation of the Requirement that He Be "Immediately Available" Throughout Such Procedures

100. To accommodate Luketich's busy practice, and allow him to perform overlapping surgeries, UPMC constructed a unique surgical "suite" for Luketich at UPMC's Presbyterian Hospital ("Presby"), which includes two, interconnected operating rooms ("OR 26" and "OR 27").

101. Luketich regularly schedules two complex surgeries to start at or very near the same time (often, around 7:00 A.M.) in OR 26 and OR 27, and plans to simultaneously conduct a third surgery scheduled at or around the same time in another Presby operating room. Because a teaching physician cannot bill for three, overlapping surgeries – and because Defendants are aware of that rule, and UPMC's schedulers and/or billing employees might flag or block an attempt to book three simultaneous surgeries under the same physician's name – the third procedure is typically booked under another attending physician's name.

102. As part of this pattern or practice, Luketich initiates the first two operations, in OR 26 and OR 27, and progresses them each to a point; but before the key and critical portions of those operations are complete, and while the patients in OR 26 and OR 27 are still under general anesthesia, Luketich leaves OR 26 and OR 27, and enters a *third* operating room, where he participates in a third, non-emergent, pre-scheduled procedure. Only after Luketich completes his portion(s) of that third procedure does he return to his customized surgical suite, and attend to the patients he left behind in ORs 26 and 27.

103. Luketich then regularly bills *all three* patients' insurance providers for his services– usually, as the "primary surgeon" or "co-surgeon."

104. For example, on November 17, 2015, Luketich performed and/or participated in – and billed for – at least six surgical procedures. According to his interoperative reports, he performed and/or participated in, and billed for:

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- a. A flexible bronchoscopy on a patient in OR 1 at UPMC's Mercy Hospital,¹ from 7:55 A.M. to 8:36 A.M.;
- b. An endoscopic myotomy on a second patient in OR 26 from 7:12 A.M. to 12:16 P.M.;
- c. A laparoscopic hernia repair on a third patient in OR 27 from 9:09 A.M. to 1:23 P.M.;
- d. A flexible bronchoscopy on a fourth patient in OR 26 from 1:28 P.M. to 1:42 P.M.;
- e. A thoracotomy on a fifth patient in OR 27 from 2:20 P.M. to 6:45 P.M.; and
- f. A thoracoscopic lung biopsy on a sixth patient in OR 14 from 6:30 P.M. to 7:30 P.M.

105. As another example, on September 26, 2016 Luketich performed and/or participated in – and billed for – at least four surgical procedures. According to his interoperative reports, he performed and/or participated in, and billed for:

- a. A laparoscopic hernia repair on a patient in OR 26 from 7:10 A.M. to 5:45 P.M.;
- b. An esophagectomy on a second patient in OR 27 from 7:16 A.M. to 6:10 P.M.;
- c. A flexible bronchoscopy on a third patient in OR 16 from 12:24 P.M. to 2:52 P.M.; and
- d. An esophageal dilation on a fourth patient in OR 16 from 6:10 P.M. to 7:03 P.M.
- 106. As another example, on February 16, 2017, Luketich performed and/or participated

in - and billed for - at least five surgical procedures. According to his interoperative reports, he

performed and/or participated in, and billed for:

- a. A sternotomy on a patient in OR 26 from 7:04 A.M. to 3:41 P.M.;
- b. A three-hole esophagectomy on a second patient in OR 27 from 7:10 A.M. to 10:01 P.M.;
- c. An esophageal dilation on a third patient in OR 16 from 10:01 A.M. to 10:50 A.M.;

¹ Mercy Hospital is a separate UPMC facility that is located at 1400 Locust Street, Pittsburgh, PA 15219, approximately *two miles* away from Presby.

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- d. An esophageal dilation on a fourth patient in OR 16 from 11:42 A.M. to 3:19 P.M.; and
- e. A lower lobe wedge resection on a fifth patient in OR 26 from 4:33 P.M. to 7:32 P.M.

107. As another example, on November 17, 2017, Luketich performed and/or participated in – and billed for – at least four surgical procedures. According to his interoperative reports and billing records, he performed and/or participated in, and billed for:

- a. A three-hole esophagectomy on a patient in OR 27 from 7:10 A.M. to 5:52 P.M.;
- b. An open roux-en-y on a second patient in OR 26 from 7:38 A.M. to 10:04 P.M.;
- c. A diverticulectomy on a third patient in OR 16 from 8:00 A.M. to 9:44 A.M.; and
- d. A laparoscopic nissen fundoplication on a fourth patient in OR 16 from 10:41 A.M. to 3:07 P.M.

108. As another example, on April 19, 2018 Luketich performed and/or participated in – and billed for – at least six surgical procedures. According to his interoperative reports and billing records, he performed and/or participated in, and billed for:

- a. A lung biopsy on a patient in OR 16 from 7:30 A.M. to 9:42 A.M.;
- b. An esophageal dilation on a second patient in OR 27 from 7:44 A.M. to 6:54 P.M.;
- c. A laparoscopic giant paraesophageal hernia repair on a third patient in OR 26 from 7:55 A.M. to 2:14 P.M.;
- d. An esophageal dilation on a fourth patient in OR 26 from 3:17 P.M. to 3:54 P.M.;
- e. An esophageal dilation on a fifth patient in OR 16 from 3:34 P.M. to 4:40 P.M.; and
- f. A catheter procedure on a sixth patient in OR 26 from 4:33 P.M. to 5:50 P.M.

109. As another example, on May 14, 2018, Luketich performed and/or participated in – and billed for – at least three surgical procedures. According to his interoperative reports and billing records, he performed and/or participated in, and billed for:

- a. An esophageal dilation and laparoscopic nissen fundoplication on a patient in OR 27 from 7:17 A.M. to 3:39 P.M;
- b. An esophagectomy on a second patient in OR 25 from 7:33 A.M. to 7:19 P.M.; and
- c. A thoracoscopic duct ligation and decortication on a third patient in OR 26 from 8:46 A.M. to 5:37 P.M.
- 110. As reflected by the above examples, Luketich routinely:
 - a. Claims to be in multiple ORs at the same time even ORs in different facilities (e.g., Mercy Hospital and Presby); and
 - b. Conducts and bills for three surgeries that overlap in time.
- 111. As reflected by the above examples, Luketich routinely cannot be and is not –

"immediately available" for the non-key or non-critical portions of a surgical procedure when he is simultaneously performing a surgical procedure on another patient in another OR.

112. Luketich – through UPP – regularly submits claims to Government Health Benefit Programs for surgical procedures that were performed when he was simultaneously leading, participating, and/or assisting in at least one other surgical procedure, and was thus not "immediately available" throughout the course of the claimed procedure, in violation of the abovedescribed conditions of payment.

ii. Luketich Regularly Delays Surgical Progress and Artificially Extends Patients' Time Under General Anesthesia, Which Results in Medically Unnecessary Anesthesia Billings, and – at Least Occasionally – Patient Harm

113. The above-described pattern or practice of regularly performing three overlapping and/or concurrent surgeries, or performing two complex surgical procedures simultaneously, often results in hours-long and medically unnecessary delays in *each* operating room. These delays: artificially lengthen surgical and anesthesia time, as Luketich generally prohibits residents, fellows, and junior attendings from substantively advancing procedures outside his presence; increase risk to patients; and – in at least some cases – have caused significant patient harm.

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114. On numerous occasions throughout the Claims Period, Luketich – through his regular practice of leaving patients mid-surgery to attend to patients in other operating rooms or matters elsewhere at UPMC – unnecessarily prolonged procedures by hours at time, and accordingly caused UPP and/or UPMC to submit inflated anesthesia claims to Government Health Benefit Programs.

115. On information and belief, Luketich's above-described concurrent surgery practice has resulted in hundreds of additional anesthesia time units being billed to Government Health Benefit Programs during the Claims Period, and those same Government Health Benefit Programs paying UPMC and/or UPP tens of thousands of dollars for those additional anesthesia time units.

116. For example, on November 17, 2017, Luketich performed and/or participated in, and then billed for, at least four surgical procedures: a nearly 14-hour laparoscopic converted to open roux-en-y on a patient in OR 26, a more-than 12-hour minimally invasive three-hole esophagectomy on a second patient in OR 27, and back-to-back, multi-hour procedures on two other patients OR 16. On information and belief, the procedure in OR 26 was extended by at least four hours, and 16 additional anesthesia time units were billed to insurance, because Luketich was simultaneously participating in multiple other complex, surgical procedures.²

iii. Luketich Does Not Participate in All of the Key and Critical Portions of His Surgical Procedures – Despite UPMC's Promises to Patients and Luketich's Attestations to the Contrary – in Violation of the Conditions for Payment

117. Through his "concurrent" surgery practice, and as reflected by the above-described examples, Luketich often cannot be – and is not – present for all of the key and critical portions of his surgical procedures.

² See Paragraphs 130, 138-141, and 144, *infra*, for similar examples.

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118. In particular, Luketich regularly fails to participate in the "time out" at the outset of surgical procedures (which UPMC defines as a critical portion of any surgical procedure), and then falsely attests and certifies that he was present for the time out, or throughout the entire procedure, or for all key and critical portions of the procedure.

119. Despite the complexity of his surgical practice, the vulnerability of his patients, and the promises UPMC makes on its website and in its advertisements, Luketich regularly skips the time-outs for his complex, multi-hour surgical procedures.

120. As an example of this pattern or practice, on April 24, 2017, Luketich performed a 13-plus hour thoracoscopy on a 46-year-old Medicare beneficiary. Despite billing CMS as the primary attending surgeon for the case, Luketich was not present for the time out at the outset of the procedure.

121. As another example of the above-described pattern or practice, on August 21, 2017, Luketich performed a flexible bronchoscopy on a 59-year-old Medicare beneficiary with ovarian cancer. Despite attesting, in the interoperative report, that he "directly performed or supervised the procedure in its entirety," and billing CMS as the primary attending surgeon for the case, Luketich was not present for the time out.

122. As another example of the above-described pattern or practice, on September 27, 2017, Luketich performed an 11-hour esophagectomy and flexible bronchoscopy on a 69-year-old Medicare beneficiary. Despite attesting, in the interoperative report, that he "was present for the entire procedure," and billing CMS as the primary attending surgeon for the case, Luketich was not present for the time out.

123. As another example of the above-described pattern or practice, on June 4, 2018,Luketich performed a 13.5-hour flexible bronchoscopy and esophagogastroduodenoscopy on a 65-

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year-old Medicare beneficiary with esophageal cancer. Despite attesting, in the interoperative report, that he "was present for the entirety of the case," and billing CMS as the primary attending surgeon for the case, Luketich was not present for the time out.

124. As another example of the above-described pattern or practice, on April 11, 2019, Luketich performed a six-hour flexible bronchoscopy on a 65-year-old Medicare beneficiary with metastatic lung cancer. Despite attesting, in the interoperative report, that he "was present for the entirety of the case," and billing CMS as the primary attending surgeon for the case, Luketich was not present for the time out.

125. By failing to participate in the time out at the outset of each surgical procedure, Luketich fails to be present for all of the critical portions of those procedures and thus violates a condition of payment for the service (as well as the applicable standard of care), abuses the patient's trust, and puts the patient's safety at risk.

126. By falsely attesting that he was present for the time out, throughout the entire surgical procedure, and/or for all key and critical portions of the procedure, and then submitting or causing UPP and/or UPMC to submit a claim for reimbursement to Medicare, Medicaid, or another Government Health Benefit Program for his physician services for that procedure, Luketich makes or causes to be made a false statement material to a claim for payment to the Government.

B. UPMC's Longstanding Knowledge of Luketich's Concurrent Surgery Practice, Its Illegality, and Its Potential for Patient Harm

127. The above-described practices – of Luketich simultaneously running complex surgical procedures in ORs 26 and 27, leaving those procedures to enter and assist in a third OR, unnecessarily prolonging surgical procedures and anesthesia times in all three ORs, skipping time outs at the beginning of surgical procedures, violating the conditions of payment for Medicare, Medicaid, and other Government Health Benefit Program reimbursement, and risking patient safety in the process – have been well-known to UPMC, *for years*.

128. In October 2015, the *Boston Globe* published an article on the issue of overlapping or concurrent surgeries.³ The article – which discussed the propriety, safety, and frequency of overlapping/concurrent surgeries at Massachusetts General Hospital and other teaching hospitals – was widely circulated amongst UPMC executives, administrators, and physicians, and caused UPMC to discuss, re-evaluate and/or draft policies regarding overlapping and concurrent surgeries, and to identify physicians or departments in potential violation of the regulations, rules, and policies concerning such surgeries.

129. Following the publication of the *Boston Globe* article, UPMC executives, administrators, and physician leaders quickly identified Luketich and the CT Department as potential sources of risk and increased scrutiny, as Luketich was well-known at UPMC to overbook surgeries, and to regularly conduct two or more complex surgeries at the same time.

130. The longtime head of UPMC's Surgical Services Oversight Committee ("SSOC")
– Jonas Johnson, M.D. – had previously chastised Luketich for overbooking surgical procedures,

³ See Clash in the Name of Care, BOSTON GLOBE (Oct. 25, 2015), available at <u>https://apps.bostonglobe.com/spotlight/clash-in-the-name-of-care/story/?p1=Clash_Landing_to-story</u>.

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and attempting to perform too many surgeries at the same time. For example, in January 2015, Dr. Johnson emailed Luketich, in response to an incident where Luketich left the operating room while one of his patients was under general anesthesia, and could not be found for more than an hour, and told Luketich that such behavior was "trouble," "not good medicine," and "irresponsible." Later that same year, Dr. Johnson again scolded Luketich via email, telling him he "appears overbooked," that his "procedures take inordinate amounts of time," and that Luketich "can only provide services to a single Medicare recipient at a time."

131. Throughout the Claims Period, Luketich ignored Dr. Johnson's reprimands and continued to schedule and perform concurrent surgeries.

132. Defendants have long known that Luketich cannot perform and bill for three surgeries that occur at the same time, and that his conduct – in repeatedly scheduling two complex surgeries at the same time, while also planning to enter a third operating room before his other two surgeries are complete; participating in, and bouncing between, all three surgeries; and billing Government Health Benefit Programs and private health insurance programs as the primary or co-surgeon for all three procedures – violates federal law.

133. In 2016, UPMC's Compliance Department disseminated a memorandum titled "Teaching Physician Documentation and Billing Rules for Procedures." A copy of that memorandum was emailed to Dr. Luketich in July 2016. In that memorandum, the Compliance Department reminded physicians that: "in order to bill for surgical, high risk, or other complex procedures, the teaching physician must be present during all critical and key portions of the procedure and be immediately available throughout the procedure." In addition, the memorandum quoted from the CMS Claims Processing Manual, noting that, "[i]n the case of three concurrent surgical procedures, the role of the teaching surgeon ... in each of the cases is classified as a

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supervisory service to the hospital rather than a physician service to an individual beneficiary and is not billable as a physician service (i.e., not billable to insurance)."

134. Also in 2016, UPMC responded to an inquiry from the United States Senate Finance Committee regarding the above-referenced *Boston Globe* article, and the issue of concurrent surgeries at teaching hospitals (like UPMC). In December 2016, that Committee issued a report on the issue, and – in so doing – quoted from the same portion of the CMS Claims Processing Manual (instructing that teaching surgeons cannot bill a Government Health Benefit Program for three concurrent surgical procedures).

135. At or around the same time, Dr. Johnson (the head of the SSOC) and UPMC's Chief Quality Officer emailed each other, and agreed that UPMC physicians cannot "service more than 2 patients simultaneously except in the case of emergency," and that doing so would be both "crazy" and "against the law."

136. In March 2016, UPMC's Vice President of Operations (Timothy Kagle), and the President of Presby (John Innocenti), met with Luketich and devised a "plan" to ensure Luketich's "availability" and "compliance with concurrency rules" going forward. In doing so, Kagle and Innocenti made clear that: Luketich could "only bill for two rooms at any one time" and created a memorandum which provided that, "[a]t no time will [Luketich] have two rooms scheduled and enter a third room to assist," except in the case of a "true emergency, which should be extremely rare." In addition, Kagle and Innocenti instructed Luketich that he could only "book into [ORs] 26 and 27 to complete concurrent cases on days that there are no other surgeons requiring [Luketich's] assistance," and told him to restrict his "surgical elective cases into one room on days that the other Thoracic surgeons are booking cases at Presbyterian with the expectation that you will be available to help."

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137. Dr. Luketich did not abide by the above-described "plan," and repeatedly violated

the rules set forth by Kagle and Innocenti.

138. For example, in July 2016, Dr. Johnson (the head of the SSOC) sent Luketich the

below email, which documented the continued "problems" with Luketich's schedule:

Message	
From:	Johnson, Jonas [/O=UPMC/OU=UPMC/CN=RECIPIENTS/CN=JOHNSONJT]
Sent:	7/6/2016 9:53:16 AM
To:	Luketich, James [luketichjd@upmc.edu]
Subject:	hi Jim

Jim,

As you know we continue to struggle with the schedule. You are incredibly busy. Problems arise when you have patients waiting for you in 2 places at once.

This leads to unhappy patients, extended delays, and potentially places the occasional patient at risk This also is wasteful of our limited OR resources

Currently we worry about the list of patients waiting for EGD. These folks are often outpatients. If you need to see or do the procedure it is essential that they be scheduled when you are available. Obviously when you are in the middle of a big case there exists a dilemma. One or the other ends up waiting.

This practice seems to be a regular occurrence. Accordingly I write to ask you to manage your schedule to reduce the waste and delay

Please let me know if I can help .

thanks

Jonas T. Johnson, MD ENM Distinguished Service Professor and Chairman Department of Otolaryngology University of Pittsburgh School of Medicine Eye and Ear Institute 203 Lothrop Street, Suite 500 Pittsburgh, PA 15213 412-647-2130 (phone) 412-647-2080 (fax)

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139. In September 2016, Joel Nelson, M.D., who was then UPMC's Chief Clinical Officer, acknowledged in an email to other UPMC executives that Luketich "is simultaneously running long, complicated cases that require his attention; when he is not there, things do not progress. [Dr. Johnson] wants to limit this at the scheduling level, **but we all know Jim [Luketich] will find work-arounds or simply ignore the rules**. So it becomes a meter [sic] of what we do when we find him not in compliance." (Emphasis added).

140. In response to said email, another UPMC executive – Leslie Davis – suggested that UPMC provide Luketich with the opportunity to develop his own "plan for correction," because, "if we mandate, [Luketich] will ignore or work-around" the rules, and put "the OR staff in the middle."

141. In September 2016, an internal, incident report claimed that:

Two patients were undergoing surgery by Dr. Luketich in [ORs] 26 and 27. The patients were both under general anesthesia with towels covering their surgical wounds. There was no surgical progress in either case between 3 and 7pm.

At 6pm, a third OR was prepared for another urgent case for Dr. Luketich. No one from the OR was able to locate Dr. Luketich by telephone, in any OR, or in his outpatient clinic until 6:45 pm when he arrived in the PACU.

142. The incident described in Paragraph 141 resulted in a slap on the wrist from UPMC leadership. Instead of stripping Luketich of his second OR, and allowing him to only "run one OR at a time rather than two" (as the then-chair of UPMC's Professional Practice Evaluation Committee first recommended), UPMC merely created another "plan"; this time, to "monitor and report any delays in surgical progress longer than 20 min[utes] in any OR," and for Luketich to "ensure that he is readily accessible by telephone or pager whenever he is not in the OR, and ensure clear communication with OR team whenever he leave [sic] the OR."

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143. The incident described in Paragraph 141 was just one example of Luketich leaving an operating room while a patient was on the table and under general anesthesia, and not returning for a prolonged, even hours-long period, as little-to-no progress occurred in the surgery. For years, UPMC anesthesiologists, fellows, residents, nurses, and other staff have complained about such incidences. On at least several occasions during the Claims Period, Luketich left the operating room mid-surgery, and then could not later be located on site by UPMC personnel, and did not immediately respond to pages, calls, and/or text messages. On other occasions, Luketich delayed surgical progress because he was out of the operating room, and in meetings or attending to other administrative matters.

144. For example, on at least 15 occasions between January 2015 and January 2019, a UPMC nurse, nurse anesthetist, or physician submitted an incident report to UPMC's "Risk Master" system claiming that Luketich was absent from the operating room for more than 20 minutes, and either no other surgeon was present, or no surgical progress was occurring.

145. Throughout the claims period, UPMC and UPP also knew that Dr. Luketich's above-described surgical practices increased the risk of harm to patients, by unnecessarily extending those patients' time under general anesthesia. In fact, as Defendants were aware during the claims period, the risk of complications to a surgical patient increases steadily for each additional minute he or she is under general anesthesia. *See, e.g., Cheng, et al., Prolonged Operative Duration Is Associated with Complications: A Systematic Review and Meta-Analysis, Journal of Surgical Research* (2018).

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146. Nonetheless, and despite the above-referenced complaints by physicians, nurses, and staff, neither UPMC nor UPP meaningfully curtailed Luketich's concurrent surgical practice during the Claims Period. To the contrary, UPMC and UPP continued to allow Luketich to perform and bill for concurrent surgeries throughout the Claims Period.

147. UPMC does not inform its surgical patients that a physician may attend to two other patients and/or participate in two other surgical procedures while the patient's procedure is ongoing. To the contrary, UPMC's informed consent form (which it revised following the October 2015 Boston Globe article on concurrent surgeries) advises patients that the "attending physician may also be caring for one other patient during [the] surgery" (Emphasis added).

148. Luketich does not inform his surgical patients that he may attend to two other patients and/or participate in two other surgical procedures while their procedure is ongoing. Neither does he inform his patients that he may leave the operating room for hours at a time while they are under general anesthesia.

149. UPMC and Luketich's failure to inform their surgical patients about Luketich's concurrent surgical practices – particularly as they advertise Luketich as a life-saving pioneer, and a reason to "Choose UPMC" when faced with potentially fatal disease – violates the trust that patients and the public place in their healthcare providers.

C. Patient Harm

150. As a result of the above-described patterns or practices, and UPMC's longstanding failure to appropriately constrain Luketich, despite knowledge of his hyper-busy schedule and the risks to patients that his surgical practices posed, numerous patients have suffered undue and grave complications, and been forced to endure costly follow-up procedures, rehabilitation, therapy, prescription regimens, and/or hospital stays – often by UPMC providers and at UPMC facilities.

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151. For example, several of Luketich's patients who endured unnecessarily long periods under general anesthesia (because Luketich left them on the operating table to attend to other patients and bill for other procedures, and/or to attend to other matters), developed compartment syndrome,⁴ and were forced to undergo fasciotomies and skin grafts during the Claims Period.

152. As a further example, many of Luketich's patients during the Claims Period developed painful pressure ulcers and/or deep tissue injuries following surgery, and were forced to obtain medical treatment for their ulcers/injuries at a UPMC facility. The risk of such injuries / ulcers generally goes up as surgical time increases.

153. As a further example, at least two of Luketich's surgical patients (a Medicare Advantage beneficiary, and a TRICARE beneficiary) suffered complications that resulted in amputations during the Claims Period. The Medicare Advantage beneficiary lost portions of a hand; the TRICARE beneficiary had a lower leg amputated.

154. On information and belief, many of Luketich's patients – including dozens of Government Healthcare Program beneficiaries – have endured lengthy hospital stays, complex follow-up procedures, and/or extended rehabilitation or therapy, and/or suffered other serious complications, as a result of Luketich's inattention, his failure to progress surgeries efficiently, and/or the patients' extreme anesthesia times.

⁴ Acute compartment syndrome is not an expected risk of surgery. It is a condition that can occur as a result of prolonged anesthesia when swelling due to damage of healthy tissue leads to increased compartment pressures, a reduction of blood flow, and tissue death.

D. Loss to the Government

155. Bills for Luketich's "physician services" are generally submitted to, and paid by, Government Health Benefit Programs in the following manner: (1) Luketich dictates, reviews, and signs an operative note, which – among other things – states that he served as the primary surgeon or co-surgeon for the procedure, attests that he was present for the key and critical portions and/or the entirety of the surgical procedure, and notes the times at which he entered and exited the operating room; (2) that operative note is then sent to UPMC's central coding and billing department, where a UPMC billing employee interprets the operative note and, through the use of a medical software program, assigns Current Procedural Terminology ("CPT") or Healthcare Common Procedure Coding System ("HCPCS") codes to the procedure; (3) UPMC then submits the bill with the applicable CPT or HCPCS codes for the surgical procedure, as well as any and all other applicable charges and ancillary fees (for, e.g., anesthesiology, radiology, and/or laboratory services), to the Government Health Benefit Programs; (4) the Government Health Benefit Program issues payment directly to UPMC; and (5) UPMC retains a percentage of the dollars received from the Government Health Benefit Program and allocates the remaining funds to the CT Department and the other groups or departments that rendered services or goods associated with the surgical procedure.

156. The bills submitted to Government Health Benefit Programs by Luketich, UPMC, and/or UPP for the following procedures during the Claims Period were materially false within the meaning of the FCA:

a. Surgical procedures for which Luketich did not participate in the time out or another key and critical component of the procedure, falsely dictated and/or attested that he was present throughout the entire procedure or for all key and critical components of the procedure, and then submitted a claim for reimbursement or payment to a Government Health Program as the primary / teaching surgeon for that procedure;

- b. Surgical procedures that Luketich performed and billed for as the primary / teaching surgeon or co-surgeon while two other surgical procedures that he billed for as the primary / teaching surgeon or co-surgeon were ongoing; and
- c. Surgical procedures that Luketich performed and billed for as the primary / teaching surgeon or co-surgeon while at least one other surgical procedure that he billed for as the primary/teaching surgeon was ongoing and not yet through all key and critical components of that second (or third) procedure.

157. The bills submitted to Government Health Benefit Programs by Luketich, UPMC, and/or UPP for unnecessarily extended anesthesia services were materially false within the meaning of the FCA.

158. Had the United States known that Luketich was: a) not participating in surgical time outs; b) conducting concurrent surgeries, including three, complex surgeries at the same time; c) leaving patients on the operating room table, and under general anesthesia, for hours at a time with little-to-no surgical progress occurring; and/or d) causing his patients to endure additional procedures, hospital stays, therapy, rehabilitation and other medical treatment because of the conduct alleged herein, it would not have paid the claims at issue.

159. On information and belief, the risk scores and capitation payments for many of the Medicare Advantage beneficiaries who were operated on by Luketich during the Claims Period were adjusted upwards in the year(s) following their surgical procedures. As alleged above, Defendants' unlawful conduct caused undue complications in some patients that resulted in further procedures, extended hospital stays, and – for Medicare Advantage beneficiaries – additional diagnosis codes that accordingly increased their prospective risk scores and MAOs' capitation payments. In those instances, the Government paid more to the MAOs – including to UPMC through its MAOs – because of Luketich's violations of the above-cited statutes, regulations, and rules.

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160. UPMC and UPP have submitted claims for reimbursement to the Government totaling tens of millions of dollars for the hospital stays, procedures, and other downstream services described above, and received tens of millions of dollars from the Government for the same. On information and belief, many of those hospital stays, procedures, and other downstream services would not have been necessary, but for Defendants' above-described conduct, including Luketich's concurrent surgical practice, inattention, and failure to progress surgeries efficiently, and/or the extreme times the patients endured under general anesthesia.

VI. CLAIMS FOR RELIEF

161. By knowingly seeking reimbursement from Government Health Benefit programs for concurrent surgeries, medically unnecessary anesthesia time, and the other, above-described practices that violated federal statutes and regulations, Defendants presented, or caused to be presented, false or fraudulent claims for payment to the United States, and/or made, or caused to be made or used, false records or statements that were material to those false or fraudulent claims for payment to the United States.

162. Defendants' violations of those federal statutes and regulations, and their false certification of compliance with said federal statutes and regulations, were material within the meaning of the FCA. Had the Government been aware of Defendants' fraudulent practices, the Government would not have paid the claims at issue.

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

163. The United States realleges and incorporates by reference the allegations in paragraphs 1-162, above.

164. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

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165. Through the acts described above, Defendants have knowingly presented or caused to be presented to the United States false or fraudulent claims for payment or approval in violation of 31 U.S.C. §3729(a)(1)(A).

166. The United States, unaware of the falsity or fraudulence of claims made or presented by Defendants, their agents, and employees, approved, paid and continue to approve and pay claims that otherwise would not have been approved or paid.

167. Defendants knew, both in fact and within the meaning of the False Claims Act, that through the acts described above they would be violating the False Claims Act, by getting false or fraudulent claims submitted or caused to be submitted by Defendants allowed or paid by the United States.

168. The United States cannot now identify each of the false claims for payment that Defendants presented or caused to be presented because the United States does not yet have access to all of the relevant records which are in Defendants' possession.

169. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount yet to be determined.

170. The United States is also entitled to the maximum penalty under 31 U.S.C. \S 3729(a)(1)(A) for each and every violation alleged herein.

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

171. The United States realleges and incorporates by reference the allegations in paragraphs 1-170, above.

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172. Through the acts described above, Defendants have knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims paid or approved by United States for work paid for by the United States in violation of 31 U.S.C. §3729(a)(1)(B).

173. The United States, unaware of the falsity of the records or statements made or used by Defendants, their agents, and employees approved, paid, and continues to approve and pay claims that otherwise would not have been approved or paid.

174. Defendants knew, both in fact and within the meaning of the False Claims Act, that through the acts described above they would be violating the False Claims Act, by making or using false statements or records material to false or fraudulent claims submitted by Defendants.

175. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount yet to be determined.

176. The United States is also entitled to the maximum penalty under 31 U.S.C. §3729(a)(1)(B) for each and every violation alleged herein.

<u>COUNT III</u> Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(G)

177. The United States realleges and incorporates by reference the allegations in paragraphs 1 - 176, above.

178. Through the acts described above, Defendants have knowingly made, used or caused to be made or used false records or statements material to an obligation to pay money to the United States and knowingly and improperly concealed, avoided, or decreased an obligation to pay or transmit money to the United States in violation of 31 U.S.C. \$3729(a)(1)(G).

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179. Defendants knew, both in fact and within the meaning of the False Claims Act, that through the acts described above they would be violating the False Claims Act, by making or using false statements or records material to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

180. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount yet to be determined.

181. The United States is also entitled to the maximum penalty under 31 U.S.C. §3729(a)(1)(G) for each and every violation alleged herein.

<u>COUNT IV</u> Unjust Enrichment

182. The United States realleges and incorporates by reference the allegations in paragraphs 1-183, above.

183. This is a claim for recovery of monies paid by the Government to Defendants, to which Defendants were not entitled, and by which Defendants have been unjustly enriched

184. As a result of the acts set forth in this Complaint in Partial Intervention, Defendants were unjustly enriched at the expense of the United States, in an amount to be determined at trial, and under circumstances dictating that, in equity and good conscience, that money should be returned to the United States.

<u>COUNT V</u> Payment by Mistake

185. The United States realleges and incorporates by reference the allegations in paragraphs 1-184, above.

186. This is a claim for recovery of monies paid by the Government to Defendants as a result of mistaken understandings of fact.

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187. The false claims which Defendants submitted to the Government were paid by the United States based upon mistaken or erroneous understandings of material fact. Had the United States known of the conduct at issue, it would not have made the payments it did.

188. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Defendants' certifications and representations, paid Defendants certain sums of money to which they were not entitled, and Defendants are thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

VII. PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that the Court enter judgment in its

favor, and against Defendants, on all Five Counts above, and enter an Order:

- A. Awarding the United States three times the actual damages suffered by the United States as a result of the false claims and/or fraud alleged in this Complaint in Partial Intervention, in accordance with the FCA, 31 U.S.C. § 3729(a)(1);
- B. Compelling Defendants to pay to the United States \$23,331, or the applicable, maximum penalty, whichever is greater, for *each* false claim submitted by UPMC, UPP, and/or Luketich, in violation of the FCA, 31 U.S.C. § 3729(a)(1);
- C. Awarding the United States all costs and expenses associated with bringing this civil action, 31 U.S.C. § 3729(a)(3);
- D. Awarding the United States a sum equal to the damages to be determined at trial, plus all of the United States' reasonable costs and expenses, on Counts IV and V;

E. Granting the United States and/or Relator any and all other relief to which they may be entitled, and which the Court deems just and proper.

Respectfully submitted,

STEPHEN R. KAUFMAN Acting United States Attorney

<u>/s/ Adam Fischer</u> ADAM FISCHER (PA 314548) Assistant United States Attorney Joseph F. Weis, Jr. U.S. Courthouse 700 Grant Street, Suite 4000 Pittsburgh, Pennsylvania 15219 Tel.: (412) 894-7431 Fax: (412) 644-6995 Email: adam.fischer@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of September, 2021, a true and correct copy of the foregoing United States of America's Complaint in Partial Intervention was served via electronic and/or first-class mail upon all counsel of record.

<u>/s/ Adam Fischer</u> ADAM FISCHER Assistant U.S. Attorney