ORIGINAL

Judge Lasnik

CV 94-00474 #00000250

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AT SEATTLE
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WESTERN DISTRICT OF WASHINGTON
BY DEPUTY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA ex rel. COSENS,

Plaintiff,

v.

PROVIDENCE MEDICAL CENTER,

Defendant.

NO. C94-474L

COMPLAINT OF UNITED STATES UPON INTERVENTION

For its Complaint, the United States of America alleges as follows:

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the False Claims Act, 31 U.S C. §§ 3729-33, and to recover damages and other monetary relief under the common law or equitable theories of unjust enrichment, payment by mistake of fact, and recoupment.

2. These claims are based upon the defendant's submission of false and fraudulent patient claims and hospital cost reports to the United States in order to obtain hundreds of thousands of dollars in payments for medical procedures and related services involving cardiac devices that had not been determined by the Food and Drug Administration ("FDA") to be safe and effective for general medical use, and therefore were not properly reimbursable

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II. JURISDICTION

3. The Court has subject matter jurisdiction to entertain this action under 28 U S C §§ 1331 and 1345, and supplemental jurisdiction to entertain the common law and equitable causes of action under 28 U.S C § 1367(a) The Court may exercise personal jurisdiction over the defendant pursuant to 31 U S C § 3732(a).

III. VENUE

4. Venue is proper in the Western District of Washington, under 31 U S.C § 3732 and 28 U.S C. §§ 1391(b) and (c) because the defendant resides and transacts business in this District and because the defendant committed acts within this District that violated 31 U S.C. § 3729.

IV. PARTIES

5. The United States brings this action on behalf of the Department of Health and Human Services (HHS), including its components, the Centers For Medicare and Medicaid Services ("CMS")(formerly known as the Health Care Financing Administration) and the Office of Inspector General, and the Medicare Program.

6. Relator Kevin D Cosens is a private citizen who has served as a sales representative and clinical support person for cardiovascular device manufacturers. This lawsuit was originally filed by the Relator on behalf of the United States under the qui tam provisions of the False Claims Act, 31 U S.C § 3730.

7. Defendant Providence Medical Center is a hospital located in Seattle, Washington. At all times relevant to this Complaint, the defendant was a participating provider in the Medicare Program.

V. THE FALSE CLAIMS ACT

8. The False Claims Act, 31 U.S.C. §§ 3729 et seq., provides, in pertinent part, that

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . a false or fraudulent claim for payment or approval, (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . . or (7) knowingly makes, uses or causes to be made or used, a false record or statement to conceal,

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> avoid, or decrease an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required, 31 U.S.C.§ 3729.

VI. THE MEDICARE PROGRAM

9. 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. Part A of the Medicare Program authorizes payment for institutional care, including inpatient hospital care and related services. See 42 U.S.C. §§ 1395c-1395i-5. Part B of the Medicare Program authorizes payment for physician services and other non-institutional medical services. See 42 U.S.C. §§ 1395j–1395w-20. Many hospitals derive a substantial portion of their revenue from the Medicare Program.

10. HHS is generally responsible for the administration and supervision of the Medicare Program. CMS, a component of HHS, is directly responsible for the administration of the Medicare Program. To assist in the administration of Medicare Part A, CMS contracts with "fiscal intermediaries," typically insurance companies, who are responsible for processing and paying claims and auditing cost reports. 42 U.S C. § 1395h. Similarly, CMS contracts with "carriers" to assist in the administration of Medicare Part B. 42 U.S C § 1395u.

11. Under the Social Security Act, 42 U.S.C. § 1395y(a)(1), the Medicare Program is only authorized to pay for items and services that are medically "reasonable and necessary." The Secretary of HHS is authorized to define what services meet that criteria. 42 U.S.C. § 1395ff(a).

12. Medicare providers have a legal duty to familiarize themselves with Medicare's reimbursement rules, including those stated in the Medicare Manuals.

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467 U.S. 51, 64-65 (1984).

13. HHS issues a manual ("the Hospital Manual"), which is distributed to all Medicare providers, to inform Medicare providers of its reimbursement policies and procedures. HHS provides similar manuals to fiscal intermediaries ("the Intermediary Manual") and to Medicare carriers ("the Carrier Manual"). These manuals ("the Medicare Manuals") are an essential source of information from CMS to providers, intermediaries, and carriers regarding Medicare coverage policies.

14. Since March 2, 1988, Medicare regulations have expressly stated that one of the "basic conditions" for a provider to receive payment from Medicare is that the provider "must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment." 42 C.F.R. § 424.5(a)(6). Prior to that time, Medicare regulations included the requirement that: "The provider shall furnish such information to the intermediary as may be necessary to assure proper payment by the program." 42 C.F.R. § 405.406(d).

15. Under the Medicare Program, CMS enters into provider agreements with hospitals in order to establish the hospitals' eligibility to participate in the Medicare Program. Upon discharge of a Medicare beneficiary patient from a participating hospital, the hospital submits claims for interim reimbursement for items and services provided to the beneficiary. Hospitals submit patient-specific claims for interim payments on a standard form. Before 1994, this was called a HCFA Form UB-82. After 1994, a modified version called a HCFA Form UB-92 was used.

16. In addition to claims for services to individual patients, Medicare providers are required to submit annually a Form HCFA-2552, more commonly known as the Hospital Cost Report, stating the amount of interim payments they have received and the amounts they believe they were entitled to receive from Medicare during the year. Medicare relies upon the Hospital Cost Report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or

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whether the provider has been overpaid and must reimburse Medicare. If the Hospital Cost Report shows that the interim payments that Medicare made to a provider exceed the amount the provider was entitled to receive, the provider must reimburse Medicare for the difference.

17 At all times relevant to this Complaint, every Hospital Cost Report contained a "Certification" that had to be signed by the chief administrator of the provider or a responsible designee of the administrator. That Certification stated in part:

> to the best of my knowledge and belief, it [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.

18. Thus, the provider was required to certify that the filed Hospital Cost Report was (1) truthful, i.e., that the cost information contained in the report was true and accurate, (2) correct, i.e., that the provider was entitled to reimbursement for the reported costs in accordance with applicable instructions, and (3) complete, i.e., that the Hospital Cost Report was based upon all information known to the provider.

19. The applicable instructions referenced in the certification included the instructions contained in the Hospital Manual, including the provisions set forth in Sections 260.1 and 210.12, which are described more fully in paragraphs 22 and 23 below.

20. The Hospital Cost Report form (Form HCFA-2552-81) reminded providers that "intentional misrepresentation or falsification of any information contained in this cost report may be punishable by fine and/or imprisonment under federal law."

21. Medicare providers are required to disclose all known errors and omissions in their claims for Medicare reimbursement (including their cost reports) to their fiscal intermediaries. 42 U.S.C. § 1320a-7b(a) states in part:

> Whoever . . . having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment . . . conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized . . . shall . . be guilty of a felony . . .

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22. Between July 1986 and November 1995, § 260.1 of the Hospital Manual stated:

> Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA.

The Intermediary Manual, § 3151.1, and the Carriers Manual § 2303.1, contained identical provisions.

23. Between July 1986 and November 1995, § 210.12 of the Hospital Manual stated in part that "[s]ervices related to non-covered services during the hospital stay" were not covered under Medicare. The Intermediary Manual, § 3101.14, and the Carriers Manual, § 2300.1, contained identical provisions.

24. Between July 1986 and November 1995, payment by Medicare for any medical procedure in which a medical device was used, or for services related to such a procedure, was expressly conditioned upon the FDA's approval of the medical device for marketing.

25. The approval of a medical device for marketing by the FDA signifies that the FDA has determined that the device is safe and effective for general medical use, and can be commercially distributed. All of the devices discussed in this Complaint were cardiac devices that had not been approved for marketing by the FDA. Rather, they were provided by the manufacturers to the defendant pursuant to an "Investigational Device Exemption," which restricted their use to carefully monitored clinical trials. The purpose of these clinical trials was to gather evidence of the safety and effectiveness of the devices in order to determine whether or not they were worthy of approval for general medical use.

26. Medicare's policy of refusing to cover procedures involving investigational medical devices did not originate in 1986. In 1977, for example, the Medicare program sent letters to all Medicare Fiscal Intermediaries advising them: "Denial of payment for a

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particular medical item or service because it is considered experimental or investigational is required by the law excluding unreasonable or unnecessary services from payment " Part A and Part B Intermediary Letters, Nos. 77-4, 77-5 (January 1977). The letter also stated that "if the service or treatment is one that is not yet generally accepted, is rarely used, novel or relatively unknown, then authoritative evidence must be obtained to establish it is safe and effective before Medicare may make payment." Thus, between 1977 and 1986, a provider who wished to bill Medicare for procedures involving the kinds of devices at issue in this case was required to provide its Fiscal Intermediary with "authoritative evidence" of the safety and effectiveness of the devices at issue when it submitted its claims.

VII. THE DEFENDANT'S MISCONDUCT

27. Between 1986 and 1995, the defendant billed Medicare for numerous procedures involving cardiac devices that had not been approved for marketing by the FDA, and for services related to those procedures. The defendant received hundreds of thousands of dollars in Medicare reimbursement for these procedures and services.

28. Based on information provided by the defendant in response to a 1994 Government subpoena, the Government has identified 161 procedures for which the defendant received improper reimbursement. In order to protect patient confidentiality, the Government is providing the defendant with a list of those procedures under separate cover. To the extent that the defendant improperly obtained reimbursement for other procedures or services involving investigational cardiac devices between July 1986 and November 1995, the Government also seeks recovery for those claims as well.

29. The defendant charged Medicare for at least 104 procedures involving atherectomy catheters manufactured by Heart Technologies, Inc. that had not received marketing approval from the FDA. These procedures are identified on the patient list that the Government is providing to the defendant under separate cover. Atherectomy catheters are devices used to cut through plaque deposits within a blood vessel.

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30. The defendant required each patient who underwent one of the procedures identified in the preceding paragraph to sign a form entitled "Consent To Act As A Research Subject For Coronary Artery Rotational Atherectomy," which stated in part:

> There may or may not be direct benefit to me from participation in this study. The investigators may learn more about the safety and efficacy of Rotational Atherectomy.

31. The defendant charged Medicare for at least 30 procedures involving implantable cardiac defibrillators ("ICD's") and defibrillator leads and patches manufactured by Cardiac Pacemakers, Inc. that had not received marketing approval from the FDA. These procedures are identified on the patient list that the Government is providing to the defendant under separate cover. ICD's and defibrillator leads and patches are devices used to regulate patients' heart rhythms.

32. The defendant required each patient who received an investigational defibrillator lead manufactured by Cardiac Pacemakers, Inc. to sign a patient consent form that stated in part:

> CPI has conducted laboratory and animal studies, with positive results, to test the ENDOTAK Lead System. As well, CPI has tested a small number of leads of an earlier version of the ENDOTAK lead system (using different wire). This version successfully converted a number of patients' irregular heart rhythm; however, these tests were discontinued due to a number of reports of conductor fracture, one of which has been associated with device failure to convert an arrhythmia that apparently proved fatal to the patient.

It also stated:

> Another automatic implantable cardioverter defibrillator lead system is currently available and is not under investigation. You are free to have this lead system implanted as an alternative.

33. The defendant charged Medicare for at least 23 procedures involving atherectomy catheters manufactured by Interventional Technologies, Inc. that had not received marketing approval from the FDA. These procedures are identified on the patient list that the Government is providing to the defendant under separate cover.

34. The defendant charged Medicare for at least 2 procedures involving pacemakers and pacing leads manufactured by Cardiac Pacemakers, Inc. that had not

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received marketing approval from the FDA. These procedures are identified on the patient list that the Government is providing to the defendant under separate cover. Pacemakers and pacing leads are used to regulate a patient's heartbeat.

35. The defendant charged Medicare for at least 1 procedure involving an atherectomy catheter manufactured by Devices for Vascular Intervention that had not received marketing approval from the FDA. This procedure is identified on the patient list that the Government is providing to the defendant under separate cover.

36. In its 1994 subpoena response, the defendant confirmed that it performed at least 1 additional procedure involving a cardiac device that had not received marketing approval from the FDA, although the defendant did not specify the manufacturer or the type of device. This procedure is identified on the patient list that the Government is providing to the defendant under separate cover.

37. The defendant had access to current copies of the Hospital Manual at all times relevant to this Complaint. Thus, it was on notice of the fact that Medicare considered medical procedures involving cardiac devices that had not received marketing approval from the FDA, and any services "related to" such procedures, to be non-covered and non-reimbursable.

38. If the defendant did not actively and regularly review the Hospital Manual to keep informed of Medicare policies, then it acted with reckless disregard for its compliance with Medicare rules and instructions, and any express or implied representations that it made that it was complying with Medicare rules or instructions were "knowingly" false within the meaning of 31 U.S.C. §3729. Alternatively, if it did review the Hospital Manual properly, then it had actual knowledge of the provisions at issue.

39. The defendant is part of the "Sisters of Providence" hospital chain. Upon information and belief, one of the other hospitals in the same chain, Providence Medical Center in Portland, Oregon ("Providence Portland"), chose to follow the Medicare rules and did not bill Medicare for procedures involving devices that had not received

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marketing approval from the FDA. Rather, Providence Portland absorbed the cost of the procedures and devices involved in the clinical trials at its hospital. Unlike its honest sister hospital, the defendant chose to bill Medicare for procedures performed in experimental clinical trials.

40. The defendant did not inform its fiscal intermediary that the claims identified in paragraphs 27 through 36 were for procedures involving investigational cardiac devices. Instead, it filled out its claim forms as if the services being billed were covered by Medicare. When the defendant submitted its claims using a HCFA Form UB-82, which had a box for "Remarks," the defendant did not explain on the form that the patient had received an investigational cardiac device. When the defendant submitted its claims using a HCFA Form UB-92, which had a column to indicate that services were "non-covered charges," the defendant listed its charges in the column for covered charges, rather than the column for non-covered charges. The defendant did not submit any supplemental documents with its claim forms that explained that the procedures being billed involved investigational cardiac devices.

41. By failing to disclose to the fiscal intermediary that its initial claims for payment were for non-covered services at the time it submitted those claims for payment, the defendant violated the False Claims Act.

42. Upon information and belief, from at least 1989 through 1995, the defendant regularly submitted Hospital Cost Reports to Medicare that were false because (a) they failed to disclose that the defendant had received reimbursement for non-covered services, and (b) they falsely certified that they had been prepared in accordance with applicable instructions.

43. By submitting these false Hospital Cost Reports, the defendant also evaded its legal obligation to reimburse money to Medicare and violated the False Claims Act.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

44. Plaintiff repeats and realleges ¶¶ 1 through 43 as if fully set forth herein.

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45 The defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States.

46. By virtue of the false or fraudulent claims made by the defendant, the United States suffered damages and therefore is entitled to statutory damages under the False Claims Act, to be determined at trial, plus civil penalties.

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False Record or Statement to Cause False Claim to be Presented) (31 U.S.C. § 3729(a)(2))

47. Plaintiff repeats and realleges ¶¶ 1 through 43 as if fully set forth herein.

48. The defendant knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States.

49. By virtue of the false records or false statements made by the defendant in support of false or fraudulent claims, the United States suffered damages and therefore is entitled to statutory damages under the False Claims Act, to be determined at trial, plus civil penalties.

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False Record or Statement to Avoid an Obligation to Refund) (31 U.S.C. § 3729(a)(7))

50. Plaintiff repeats and realleges ¶¶ 1 through 43 as if fully set forth herein.

51. The defendant knowingly made, used or caused to be made or used false records or false statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States.

52. By virtue of the false records or false statements made by the defendant to avoid an obligation, the United States suffered damages and therefore is entitled to statutory damages under the False Claims Act, to be determined at trial, plus civil penalties.

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FOURTH CAUSE OF ACTION

(Payment by Mistake of Fact)

53. Plaintiff repeats and realleges ¶¶ 1 through 43 as if fully set forth herein.

54. This is a claim for the recovery of monies paid by the United States to the defendant as a result of mistaken understandings of fact.

55. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of the defendant's certifications and representations, paid the defendant certain sums of money to which it was not entitled, and the defendant is thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

FIFTH CAUSE OF ACTION

(Unjust Enrichment)

56. Plaintiff repeats and realleges ¶¶ 1 through 43 as if fully set forth herein.

57. This is a claim for the recovery of monies by which the defendant has been unjustly enriched.

58. By directly or indirectly obtaining Government funds to which it was not entitled, the defendant was unjustly enriched, and is liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

SIXTH CAUSE OF ACTION

(Recoupment of Overpayments)

59. Plaintiff repeats and realleges ¶¶ 1 through 43 as if fully set forth herein.

60. This is a claim for recoupment, for the recovery of monies unlawfully paid by the United States to the defendant contrary to statute or regulation.

61. The United States paid the defendant certain sums of money to which it was not entitled, and the defendant is thus liable under the law of recoupment to account and return such amounts, which are to be determined at trial, to the United States.

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PRAYER FOR RELIEF

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

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

2. On the Fourth, Fifth and Sixth Causes of Action, for payment by mistake, unjust enrichment, and recoupment, for the damages sustained and/or amounts by which the defendant was unjustly enriched or by which the defendant retained illegally obtained monies, plus interest, costs, and expenses, and all such further relief as may be just and proper.

DATED this 16th day of December, 2002.

Respectfully submitted,

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