

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 04-cv-00018-RPM-OES

UNITED STATES OF AMERICA *ex rel.* BRENDA MARCH

Plaintiff,

v.

COCHLEAR AMERICAS, INC. and COCHLEAR LIMITED

Defendants.

AMENDED COMPLAINT (FILED UNDER SEAL)

Brenda March, acting as Relator on behalf of the Government of the United States of America (the “Relator”), states as follows in this Complaint against Defendants Cochlear Americas, Inc. (“Cochlear Americas”) and Cochlear Limited (“Cochlear Limited”) (collectively, “Defendants”):

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America, arising from false statements and claims made and presented by the Defendants and/or their agents, employees and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended (the “Act”). The violations of the Act involve claims for excessive Medicare and Medicaid payments due to overstatement of the cost of Cochlear Americas hearing devices caused to be submitted for reimbursement by Defendants. Such overstatements have continued since at least the beginning of 1998, which Defendants

knew were false, exaggerated and/or overstated. In violation of their duty to report known errors resulting in unwarranted overpayment of Medicare and Medicaid funds, Defendants likewise concealed such errors from Government agents in order to keep funds to which they were not entitled.

2. The Act provides that any person who knowingly submits or causes to be submitted a false or fraudulent claim to the Government for payment or approval is liable for civil penalty of up to \$10,000 for each such claim submitted or paid, plus three times the amount of the damages sustained by the Government. Liability attaches both when the defendant knowingly seeks payment that is unwarranted from the Government and when false records or statements are knowingly created or caused to be used to conceal, avoid or decrease an obligation to pay or transmit money to the Government. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring an action for himself or herself (in this case, the Relator) and for the Government and to share in any recovery. The complaint is filed under seal for sixty days (without service on the defendants during that period) to enable the Government to conduct its own investigation without the defendants' knowledge and to determine whether to join the action.

3. Based on those provisions, Relator seeks to recover damages and civil penalties arising from Defendants' presentation of false records, claims and statements to the United States Government and its agents and state Medicaid programs relating to the Medicare and Medicaid programs and in connection with Defendants' overstatement of the cost of medical devices produced by Cochlear Limited, distributed by Cochlear Americas and implanted by Physicians (hereinafter defined) in patients. Relator also seeks to recover damages arising from Defendants'

unlawful practice of permitting records that Defendants know contain erroneous information to be relied upon by the Government's fiscal intermediaries as the basis upon which to pay excessive reimbursement from federal funds, and for false claims arising from Defendants' violations of the federal Anti-Kickback Act, 42 U.S.C. § 1320 a-7-b (b) (1994 and 1996 Supp.).

II. PARTIES AND NON-PARTIES

4. At the time of the events relevant to this lawsuit, the Relator, Brenda March ("Ms. March"), was a resident of Centennial, Colorado. She has since moved to Cheyenne, Wyoming. Ms. March brings this action for violations of 31 U.S.C. § 3729 *et seq.*, on behalf of herself and the United States Government, pursuant to 31 U.S.C. § 3730(b)(1). Ms. March has a strong background in finance, having served as an analyst, controller, and a Vice President of Finance for a large U. S. corporation prior to joining Cochlear Americas. She was first employed at Cochlear Americas in 1997. She was originally hired as Vice-President of Finance and later was promoted to Vice-President of Customer Care. She also acted as Vice-President of Customer Service and Commercial Development. At all times relevant hereto, she was also a director of Cochlear Americas. Ms. March has personal knowledge of the false records, statements and/or claims presented to the Government for the benefit of the Defendants named herein and Defendants' fraudulent exaggeration of the true cost of such devices and other wrongdoing.

5. Defendant Cochlear Americas is a Delaware corporation, and is a wholly owned subsidiary of Cochlear Limited, an Australian business entity. Cochlear Americas distributes medical devices (manufactured by Cochlear Limited) that are implanted in patients to significantly improve hearing capabilities for those with severe to profound hearing loss.

Cochlear Americas' headquarters are located in Englewood, Colorado, although it distributes and sells its hearing devices in all fifty states.

6. Defendant Cochlear Limited is an Australian business entity. Cochlear Limited developed and now manufactures the hereinafter defined "Implant System." Cochlear Limited's headquarters are located in Sydney, Australia. However, Cochlear Limited works with Cochlear Americas in the United States to incentivize Physicians (defined below) to influence the purchase of cochlear implant systems.

7. Non-parties to this Complaint are certain physicians, surgeons, audiologists, and related clinics owned, operated or controlled by those individuals located and practicing in the United States, which influence and direct hospitals, acting as purchasing agents, to purchase Cochlear Americas implant devices and related Cochlear Americas products. Those certain physicians, surgeons, audiologists and related clinics are referred to herein collectively as the "Physicians." The Physicians are located and practice throughout the United States.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

9. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which provides that "[a]ny action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred."

§ 3732(a) also authorizes nationwide service of process. Defendant Cochlear Americas, during the relevant period, was located in, and/or transacted business in, the District of Colorado. Similarly, Cochlear Limited has conducted business in Colorado during the relevant period.

10. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant Cochlear Americas can be found in, and transacts business in the District of Colorado, and because violations of 31 U.S.C. § 3729 described herein occurred within this judicial district. Venue is proper with respect to Cochlear Limited because Defendant Cochlear Limited transacts business in the District of Colorado, and because some of the violations of 31 U.S.C. § 3729 described herein occurred within this judicial district.

IV. GENERAL ALLEGATIONS

A. Cochlear Partners/Cochlear Advantage

11. Following manufacture and delivery by Cochlear Limited to Cochlear Americas, Cochlear Americas distributes the Cochlear Americas implant system (“Implant System”) to hospitals and others. The Implant System consists of an internal device (implanted under the skin by a Physician), two external processors (one worn behind one ear plus a spare) and related accessories. Cochlear Americas sells the large majority of such hearing implant devices for patients in the United States with severe to profound hearing loss. With regard to Medicare and Medicaid patients, Cochlear Americas works closely with physicians and hospitals, in an attempt to maximize Medicare and Medicaid reimbursement. A depiction of the process by which Cochlear Americas sells its product and by which hospitals obtain reimbursement from Medicare (or Medicaid, or private insurance) for purchase of the Implant System, is attached as Exhibit A.

12. As demonstrated in Exhibit A, the hospital acts primarily as a purchasing agent. At the request and direction of Physicians that use hospital facilities, the hospital purchases the Cochlear Americas Implant System, and Cochlear Americas invoices the hospital for payment. Most hospitals then pay Cochlear Americas the invoice list price for the Implant System, which varied between \$18,000 -\$24,500 during the period 1997 through 2003. The hospital then sends that invoice list price to Medicare (or Medicaid, or private insurance) for reimbursement. Physicians implant the system at the hospital and bill Medicare (or Medicaid or private insurance) separately for their services.

13. In order to incentivize Physicians to direct hospitals to purchase Cochlear Americas implants (as opposed to the implants of Cochlear Americas competitors), in 1998, Cochlear Americas implemented a nationwide program known as the Cochlear Partners Program. Pursuant to the Cochlear Partners Program, a Physician was required to sign a contract, either exclusive or non-exclusive, with Cochlear Americas. Pursuant to that contract, the Physician received “credits” good towards free Cochlear Americas products and/or systems. The hospital, the actual purchaser of the Cochlear Americas implant, was not a party to this agreement, and neither received a benefit from the Cochlear Partners Program nor reduced its invoice to Medicare, Medicaid or private insurance for the amount of such benefits. The hospital was not made aware of the discounts and credits to the Physicians. Not surprisingly, Physicians who signed an exclusive contract with Cochlear Americas received more free products and/or systems.

14. At the end of 1999, Cochlear Americas abolished the Cochlear Partners Program and introduced the Cochlear Advantage Program nationwide. The Cochlear Advantage Program

eliminated the requirement for a signed contract. Instead, the Cochlear Advantage Program relied upon a verbal agreement between Cochlear Americas and Physicians whereby Physicians would receive credits based on purchases. The credit level would be determined by the volume of Cochlear Americas products that a Physician directed for purchase (bronze, silver, and gold levels). In other words, those Physicians who directed the purchase of a greater volume of Cochlear Americas products received more credits. Like the Cochlear Partners Program, Physicians could use credits earned for free products or systems. Unlike Cochlear Partners, the Physicians could also use the credits for other valuable consideration, including cash payments or other direct compensation. Again, the hospital, which acted as the purchasing agent, was not a party to this verbal agreement. Further, no direct notification was given to the hospitals regarding the credits. Like the Cochlear Partners Program, the Cochlear Advantage Program constituted a form of improper discounts and/or “kickbacks” to Physicians.

15. The Cochlear Advantage Program commenced January 1, 2000. In 2001, it was modified to exclude credits for the Implant System for Medicare and Medicaid patients. However, Cochlear Americas compensated the Physicians for this loss by increasing credits for non-Medicare/Medicaid Implant Systems such that the net credits received were the same. In other words, the Physicians still had the same incentive to direct hospitals to purchase the Implant System for Medicare/Medicaid patients as before.

16. The Cochlear Advantage Program was discontinued on December 31, 2002. However, Physicians were permitted to use accrued credits to receive products and/or systems or other compensation through June 2003.

17. Cochlear Americas' marketing department managed both the Cochlear Partners and Cochlear Advantage Programs. Although the Cochlear Partners and Cochlear Advantage Programs were discontinued, Cochlear Americas has expanded other existing programs, and developed new ways to provide financial remuneration to Physicians to incentivize them to direct hospitals to purchase Cochlear Americas products. Those incentives are described in Section E below.

B. Medicare Reimbursement

18. Medicare is a federally funded health insurance program. Medicare was created in 1965 in Title XVIII of the Social Security Act. Medicare has two parts:

- a. Part A, the basic plan of hospital insurance, which covers the cost of hospital services and related ancillary services such as home health care agencies and skilled nursing facilities; and
- b. Part B, which covers the cost of physicians services and other ancillary services not covered by Part A.

19. Medicare reimbursement is available to hospitals for medical devices they purchase which are implanted by Physicians in patients, including the Cochlear Implant System. The U.S. Government, based upon a complicated formula, determines the amount of reimbursement for each such device annually. The invoiced amount (*i.e.* the invoiced cost) submitted by the entity (usually a hospital) purchasing the device is a significant factor in determining the level of Medicare reimbursement.

20. With respect to Cochlear Americas, after the hospital purchases and pays for an Implant System, the hospital submits the invoice amount to the applicable Medicare-related governmental agency, Department of Health and Human Services, Centers for Medicare &

Medicaid Services (“CMS”) for reimbursement. The reimbursement is based on: invoice (less discounts) for the Implant System plus facility fee costs (operating room and associated costs) plus a mark-up (often 300 %). The Physician or surgeon bills Medicare for his/her fee separately and is reimbursed separately.

21. CMS then reimburses based on a fixed amount for the Implant System. The fixed amount is calculated based on invoice prices actually submitted by all hospitals in the United States in the previous year. CMS then eliminates the minimum and maximum charges and develops a median charge. Then it reduces that amount by approximately 13% to obtain an adjusted reimbursement amount for the next fiscal year. The reimbursement amount in fiscal year 2002 for the Implant System was \$19,280. The reimbursement amount in fiscal year 2003 is \$19,179 and is proposed to be \$21,395 in fiscal year 2004.

22. The amount the hospital actually receives from Medicare is further adjusted from the above-stated amounts. Specifically, the amount the hospital receives is higher or lower based on a wage index that accounts for differences in wages in different areas of the United States.

23. Despite the adjustments created by the Medicare reimbursement procedures, however, one thing is clear: the invoice amount sent by Cochlear Americas to hospitals, and in turn submitted by hospitals to Medicare, is a very significant factor in determining the level of Medicare reimbursement to hospitals who purchase Implant Systems.

C. Loss Resulting from Excessive Medicare Reimbursement

24. As described above, the U.S. Government calculates Medicare reimbursements annually. The level of reimbursement for a Cochlear Americas implant purchased by a hospital is dependant, in large part, on the amount of the invoice submitted by the hospital to Medicare.

Relevant to this Complaint, the invoiced amounts submitted by the hospitals to Medicare were and are artificially high. The invoiced amounts do not account for the discounts, in the form of credits, given to Physicians. Under the Cochlear Partners/Advantage Programs, such discounts total between approximately \$1,500 and \$ 4,170 per Implant System, depending on the volume directed for purchase by a particular Physician. Therefore, taking the value of the financial incentives to Physicians into account, the invoiced price for an Implant System purchased should have been significantly less. Due to the credits given by the Cochlear Partners/Advantage Programs, hospitals, therefore, have unwittingly invoiced Medicare far more than the true invoice price/cost for each Implant Systems purchased.

25. The result is that when Medicare reimbursements have been calculated each year since the Cochlear Partners Program was instituted, Medicare has set reimbursement rates at a level higher than such rates otherwise would have been, had the invoices reflected the actual cost of the Implant Systems (*i.e.*, invoice price less benefits to Physicians). Therefore, since at least 1998, Medicare reimbursements to hospitals for Cochlear Implant Systems have been artificially high due to the improper financial incentives paid by Cochlear Americas to Physicians. Cochlear Americas, therefore, has willingly and knowingly caused such false claims to be submitted to Medicare. While the Relator has personal knowledge of these allegations, certain information in support of these allegations is exclusively in the hands of Defendants and will not be available until discovery commences.

D. Medicaid Reimbursement and Loss From Excessive Payments

26. Medicaid was created in 1965 in Title XIX of the Social Security Act. Funding for Medicaid is shared between the federal government and those states participating in the

program. Funding varies among states, but usually approximates an equal division. Each state has a unique formula for calculating reimbursement rates for medical devices. Certain states, for example, reimburse either on a predetermined maximum allowable cost or based on the provider's usual and customary charge. In either event, however, the invoiced cost of the medical device is a factor in determining the level of reimbursement.

27. With respect to the Implant System, as a result of the Cochlear Partners/Advantage Program, Physicians directed hospitals to purchase Cochlear Implant Systems for Medicaid patients, for the reasons described above. However, due to the credits paid pursuant to the Cochlear Partners/Advantage Program to Physicians, invoice cost submitted by hospitals for Medicaid reimbursement is overstated. Therefore, reimbursement rates are also overstated, resulting from the exaggerated and false claims for reimbursement for Implant Systems for Medicaid patients. While Relator has personal knowledge of these allegations, certain information in support of these allegations is exclusively in the hands of the Defendants and will not be made available until discovery commences.

E. Violation of Anti-Kickback Statute

33. The federal Anti-Kickback Act, 42 U.S.C. § 1320 a-7 b (b) (1994 and Supp. 1996) imposes penalties for the payment, solicitation, or receipt of "any remuneration (including any kind of kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in return for referrals that will be paid for under federal healthcare programs. Despite the prohibition contained in the Anti-Kickback Act, Defendants have engaged in conduct that violates that statute. Specifically, Defendants have engaged in and may continue to engage in activities such as the following:

- a. Cochlear Americas has made direct cash payments to Physicians and/or paid for trips to exotic locations for Physicians and their spouses or guests and families. The express purpose of such payments are and were to encourage Physicians to direct hospitals, as purchasing agents, to purchase Cochlear Implant Systems.
- b. Cochlear Americas has sponsored and funded the creation of certain “advisory boards.” All such advisory board members are Physicians who direct the purchase of significant quantities of Cochlear Americas products. Meetings of such board members frequently include: (i) airfare for spouses or guests (who are not board members) (ii) first-class airline tickets (that are unnecessary) and (iii) significant free time and recreational activity for board members paid for by Cochlear Americas. In practice, these programs constitute a means to improperly funnel compensation to Physicians.
- c. Cochlear Americas has furnished payments to Physicians to pay the salaries of certain staff or clinic employees, donations to support clinic general operating expenses, unrestricted grants for research not identified as necessary (or even documented), golf tournaments, free products, etc. These contributions constitute improper compensation from Cochlear Americas to Physicians for directing hospitals to purchase Cochlear Implant Systems.

- d. Cochlear Americas has, for years, provided gifts to Physicians that encourage hospitals, as purchasing agents, to purchase Cochlear Americas products. For example, in 2003 Cochlear Americas specifically authorized and paid for gift baskets and other products for Physicians who directed hospitals to purchase Cochlear Implant Systems.
- e. Cochlear Limited has created, funded, and managed the VISTA (Visiting Implanting Specialists to Australia) Program. By this program, Cochlear Limited arranges to have groups of Physicians flown to Australia for an approximately seven-day visit semi annually. Ostensibly, to obtain input from Physicians on new cochlear technology, this program is, in reality, a marketing junket. Cochlear Limited, indeed, chooses to fly over those Physicians who are considered marketing targets, not those best qualified to comment on new technology. The trip is organized by Cochlear Limited, and invitations are created by Cochlear Limited and sent by Cochlear Americas. The trips are completely paid for by Cochlear Limited (except airfare, which is paid by Cochlear Americas).
- f. Cochlear Americas works closely with Cochlear Limited in connection with the VISTA Program. Cochlear Americas provides Cochlear Limited with information regarding which Physicians to target as part of its marketing effort pursuant to the VISTA Program.
- g. Cochlear Limited, in conjunction with Cochlear Americas, has also implemented a program known as the Streamline Fitting Study. Pursuant

to this study, sponsored and approved by Cochlear Limited, Physicians were flown in from around the United States to an event at the Broadmoor Hotel in Colorado Springs, Colorado, in November of 2003. In order to qualify to attend the function, Physicians (primarily audiologists) were required to agree to direct purchase of between five and ten Implant Systems and provide Cochlear Americas certain outcome evaluations after implants were completed. In reality, however, this function was primarily an enticement to Physicians to direct purchase a significant number of Cochlear Implant Systems products.

- h. Representatives of Cochlear Limited frequently visit the United States and meet with Physicians. On information and belief, Cochlear Limited has required and directed Cochlear Americas to make direct cash payments to Physicians or their associated clinics as an inducement to purchase more Implant Systems and Cochlear products. Such payments, individually, amount to tens of thousands of dollars since the beginning of 1998.

34. As a result of this conduct, Defendants have caused hospitals to submit false claims for implants and such claims are improper and/or excessive because of the kickbacks, discounts or payments from Cochlear Americas and Cochlear Limited to the Physicians. This conduct is separate from and in addition to the compensation Defendants provided to the Physicians relating to the Cochlear Partners/Advantage Programs. The submission of these and other false claims render Defendants liable for violation of the False Claims Act.

Count I

[Substantive violations of False Claims Act] 31 U.S.C. § 3729 (a)(1), and (a)(2)

35. Plaintiff/Relator realleges and incorporates by reference the allegations made in each of the foregoing paragraphs of this Complaint.

36. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729 - 32, as amended.

37. Through the acts described above, Defendants and their agents and employees knowingly presented and caused to be presented to the United States Government, and state governments participating in the Medicaid program, false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare and Medicaid.

38. Through the acts described above and otherwise, Defendants and their agents and employees knowingly made, used and caused to be made, or used false records and statements to the United States Government and state agencies which resulted in overpayment of Medicare and Medicaid reimbursement. Defendants also knowingly failed to disclose to the Government material facts that would have resulted in reduction of such payments.

39. The United States, its fiscal intermediaries, and state Medicaid programs, unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants and their agents and employees, paid and continued to pay excessive amounts for Medicare and Medicaid reimbursement that would not have been paid if the truth had been known.

40. The United States, its fiscal intermediaries, and state Medicaid programs, unaware of the falsity of the records, statements, and claims made or cause to be submitted by Defendants

- or of their failure to disclose material facts which would have reduced government obligations
- have not recovered Medicare and Medicaid funds that would have been recovered otherwise.

41. By reason of Defendants false records, statements, claims, and omissions, or the causation thereof, the United States and state Medicaid programs have been damaged in an amount in excess of \$5,000,000.

Count II

[False Claims Act Conspiracy] 31 U.S.C. § 3729 (a)(3) and § 3732 (b).

42. Relator realleges and incorporates by reference the allegations in each of the foregoing paragraphs of this Complaint.

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

44. Through the acts as stated above and otherwise, the Defendants have entered into a conspiracy or conspiracies among themselves, the Physicians, and with others to defraud the United States Government and state Medicaid programs by causing false and fraudulent claims to be allowed and paid. Defendants have also conspired to omit disclosing and have actively concealed facts which, if known, would have reduced Government payments. Defendants have taken substantial steps in furtherance of those conspiracies, *intra alia*, by knowingly participating in improper programs or offering or accepting other financial remuneration which resulted in invoices being submitted to Medicare or Medicaid for reimbursement in excess of the true cost of the underlying Implant Systems. As a result, the United States and states participating in Medicaid programs have been damaged.

45. In addition, provision of financial remuneration to Physicians by Cochlear Americas and Cochlear Limited violates the Anti-Kickback Act and has resulted in submission of false claims to the Government and states participating in Medicaid programs. The United States, and states participating in Medicaid programs, are unaware of the foregoing conspiracies or the falsity of the records, statements, and claims made or caused to be made by Defendants and their agents, employees, and co-conspirators, and as a result thereof, have paid and continue to pay greater Medicare and Medicaid reimbursement than would otherwise have been paid.

46. By reason of Defendants' conspiracies and the acts taken in furtherance thereof, the United States and state Medicaid programs have been damaged in an amount in excess of \$5,000,000.

WHEREFORE, Plaintiff/Relator prays for judgment against Defendants as follows:

- (1) That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*;
- (2) That the Court enter judgment against the Defendants in the amount equal to three times the amount of damages the United States has sustained as a result of Defendants actions, as well as a civil penalty against each Defendant of \$10,000 for each violation of 31 U.S.C. § 3729;
- (3) That Plaintiff/Relator be awarded the maximum amount pursuant to § 3730 (b) the Federal/Civil False Claims Act;
- (4) That Plaintiff/Relator be awarded all costs and expenses of this action, including attorney's fees; and
- (5) That the United States and Plaintiff/Relator receive all such other relief as this Court deems just and proper.

Jury Demand

Pursuant to Rule 38 of the F.R.C.P, Plaintiff/Relator hereby demand trial by jury.

Respectfully submitted this 10th day of January 2007.

s/ Dana L. Eismeier _____

Dana L. Eismeier

Michael J. Norton

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Brenda March

Relator's Address:

Brenda March

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CERTIFICATE OF SERVICE

I hereby certify that on January 10, 2007, I electronically filed the foregoing **AMENDED COMPLAINT (FILED UNDER SEAL)** with the Clerk of Court using the CM/ECF System, and that I have mailed or served the document or paper to the following non-CM/ECF participants in the manner indicated by the non-participant's name:

By U.S. Mail:

John William Suthers
Assistant U. S. Attorney
United States Attorney's Office
for the District of Colorado
1225 17TH Street, Suite 700
Denver, CO 80202

s/ Dana L. Eismeier _____
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