

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 05-10557-RWZ

UNITED STATES, ex rel.
JEFFREY J. BIERMAN

v.

ORTHOFIX INTERNATIONAL, N.V., et al.

MEMORANDUM OF DECISION

April 11, 2016

ZOBEL, J.

Plaintiff-Relator Jeffrey Bierman has alleged that DJO¹ defrauded Medicare by fraudulently selling bone-growth stimulation devices. Following a previous round of summary judgment, see Docket # 358, Bierman's sole remaining theory of liability under the False Claims Act, 31 U.S.C. §§ 3729 et seq.—and a host of state and local analogs²—is that DJO trained physicians to recommend inflated estimated lengths of

¹ "DJO" refers to DJO, Inc., and ReAble Therapeutics, Inc.

² The relator asserts claims under the following: the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201 et seq.; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 2-308.13-21; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081-092; the Georgia State False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21-29; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-115.5 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46:437.1-14; the Massachusetts False Claims Act, Mass. Gen. L. ch. 12, §§ 5B et seq.; the Michigan Medicaid False Claims Act, MCL §§ 400.601 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 et seq.; the New Hampshire Medicaid Fraud and False Claims Act, RSA §§ 167.58 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-12-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law §§ 187-194; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-182 et seq.; the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.3 et seq.; and the Chicago False Claims Act, Chicago Municipal Code ch. 1-21 et seq.

need for its device. In support of this theory, Bierman has marshalled two experts, Yadin David and Jonathan Williams, who purport to show that only Bierman's hypothesis—illegal coaching—can explain certain statistics generated from DJO's records.

DJO has moved for summary judgment and to exclude the testimony of both experts. DJO's motion for summary judgment is allowed, and its motions to exclude are denied as moot.

I. Background

Previous opinions have already offered a detailed description of the facts underlying litigation. See United States ex rel. Bierman v. Orthofix Int'l, N.V., 748 F. Supp. 2d 123, 125–27 (D. Mass. 2010). I therefore recite here only those facts relevant to DJO's motion for summary judgment in the light most favorable to Bierman, see Prescott v. Higgins, 538 F.3d 32, 39 (1st Cir. 2008).

According to Bierman, DJO, between 2004 and 2009, coached prescribing physicians when marketing its bone-growth stimulation devices. These devices, which DJO—and all other manufacturers of comparable devices—offered for purchase, not for rental,³ have a useful life of nine months. Medicare requires Certificates of Medical Necessity (CMNs), particular to bone-growth stimulators, to accompany each prescription. The CMN's Section B requests patient-specific information such as diagnosis and medical history, and Section D requires an attestation from the signing physician that all information contained within the form is true. See CMS, Form CMS-847. Section B also requests—under the heading Estimated Length of Need—that the

³ Bierman previously alleged that the refusal to offer a rental option for its devices violates the False Claims Act. In an earlier round of summary judgment, this court held against this theory: the relevant regulation leaves the supplier—i.e., DJO—with discretion to rent or sell devices to Medicare. See Docket # 358.

prescribing physician estimate how long a patient will need to use the device. See id. The vast majority of DJO's CMNs list a nine-month recommendation: eighty percent have a nine-month estimated length of need, and seventy-five percent of physicians who prescribe DJO devices estimate nine months on every form they fill out.

From these statistics, Bierman infers that DJO has coached physicians to unreflectively estimate a nine-month length of need in lieu of exercising their medical judgment. By coaching physicians to list a nine-month estimated length of need on the CMNs for its devices and sending them alongside its claims to Medicare, Bierman claims, DJO has submitted to Medicare false claims for device payments. DJO did instruct its employees that it preferred CMNs to state a nine-month estimated length of need, though it argues that estimated lengths of need are immaterial to its Medicare compensation given that (1) Medicare purchases DJO devices instead of renting them; and (2) applicable Medicare guidance makes no mention of estimated length of need as relevant to its decision to pay.

II. Standard

Courts “shall grant summary judgment” absent any “genuine dispute as to any material fact.” Fed. R. Civ. P. 56(a). Summary judgment is inappropriate when “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

III. Discussion

DJO has argued, persuasively, that estimated lengths of need on the CMNs are immaterial to Medicare's decision to pay and are thus not actionable under the False Claims Act. The crux of this argument is that DJO and all of its relevant competitors sell devices to patients with no option for rental, rendering the physician's estimated length

of need irrelevant to Medicare’s decision to purchase—or not purchase—a device for a given patient.

The False Claims Act imposes liability upon “any person who . . . knowingly presents . . . a false or fraudulent claim for payment or approval.” 31 U.S.C.

§ 3729(a)(1)(A) (2012).⁴ Falsity immaterial to the government’s decision to pay is not actionable. See United States ex rel. Loughren v. Unum Corp., 613 F.3d 300, 307 (1st Cir. 2010). Falsity is material only “if it has a natural tendency to influence, or is capable of influencing, the decision of the decisionmaking body to which it was addressed.” Id. at 307.

DJO’s decision to sell its devices instead of renting them leaves physicians’ estimated lengths of need incapable of influencing Medicare’s decision to pay for those devices. Medicare purchases devices at a flat rate that does not depend whatsoever on that device’s estimated length of need. See 42 C.F.R. § 414.220(b)(1) (2016). Likewise, Medicare’s National Coverage Determinations Manual, which sets forth the criteria under which Medicare will or will not pay for certain devices or services, makes no mention of estimated length of need in its discussion of bone-growth stimulators such as those sold by DJO. See CMS, National Coverage Determination Manual § 150.2 (2005). Nor has any Medicare Administrative Contractor⁵ promulgated any local coverage

⁴ The Fraud Enforcement and Recovery Act of 2009 (FERA) substantially amended the False Claims Act. Although Bierman asserts both pre- and post-FERA claims here, the distinctions between the statute have no bearing on this motion: the relevant pre-FERA proscription reached “[A]ny person who . . . knowingly presents . . . to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1) (1986).

⁵ Medicare Administrative Contractors may incorporate additional coverage criteria—known as local coverage determinations—beyond what appears in the National Coverage Determination Manual. See 42 U.S.C. § 1395ff(f)(2)(B) (2012).

determination that references estimated length of need as a factor when considering reimbursement. This pronounced absence of estimated length of need from lists of criteria developed to guide Medicare's reimbursement decisions demonstrates that Medicare does not consider estimated length of need material to those decisions. Cf. Barnhart v. Peabody Coal Co., 537 U.S. 149, 169 (2003) (“[I]tems not mentioned [in a statute] were excluded by deliberate choice, not inadvertence.”).

Bierman offers several arguments against this conclusion, none of which disturb it. First, Bierman relies on the CMN itself, arguing that Medicare would not request—and would not require physicians to certify the truth of—information immaterial to its payment decisions. Because estimated length of need appears on the CMN, the argument goes, it must be material. This, however, ignores two facts: CMS uses the same form for rented and purchased devices, and CMS pays a flat rate when it purchased devices. This means—and DJO agrees—that estimated length of need may well be material to Medicare when determining whether or not to cover device rental, but not device purchase. As it relates to device rental, the estimated length of need determines the price that Medicare will pay, and price is an unambiguously material condition under the FCA. See United States ex rel. Shemesh v. CA, Inc., 89 F. Supp. 3d 36, 51 (D.D.C. 2015). As to device purchase, however, estimated length of need is irrelevant: during the period at issue, Medicare had no option to rent DJO or other bone-growth stimulators, making estimated length of need incapable of influencing Medicare's decision to rent instead of purchase. Nor could estimated length of need determine the price Medicare paid to purchase the device, as regulations specify that Medicare must purchase devices for a flat fee. See 42 C.F.R. § 414.220(b)(1).

Second, Bierman argues that DJO's policy of coaching physicians to request nine-month estimated lengths of need demonstrates that Medicare considered lengths of need to be material. This is incorrect: although the record suggests that DJO did have such a policy, that has no bearing on Medicare's position as to the relevance of estimated lengths of need. Further, DJO's coaching policy does not even demonstrate conclusively its own belief as to materiality: it is equally consistent with confusion over a query it believed irrelevant given both the purchase-only marketplace and Medicare reimbursement regime.

Third, Bierman points to a charging document against Orthofix—formerly a defendant in this case—in which the Department of Justice stated its belief that Orthofix's alleged coaching of physicians to list a nine-month estimated length of need was material to Medicare's decision to pay for those devices. Setting aside concerns of admissibility, this has no bearing on Bierman's arguments: the Department of Justice's position in a criminal information carries no weight when interpreting the meaning of the False Claims Act, of Medicare regulations, or of Medicare guidance. Cf. United States v. Mead Corp., 533 U.S. 218 (2001) (defining the outer limits of deference to administrative agencies).

Finally, Bierman has gestured to the government's pending investigation as to whether or not Medicare could save money by renting bone-growth stimulators instead of purchasing them. Whether or not such an investigation confirms the government's current interest in the estimated lengths of need for such devices—which may influence decisions to cover rentals, but not purchases, for certain patients—it has no bearing on

the materiality of estimated lengths of need from 2004 until 2009, the time at issue in this litigation.

Because Bierman cannot point to any fact in this record to show that estimated lengths of need are material to Medicare's decision to purchase DJO's bone-growth devices, Bierman cannot sustain his False Claims Act action under this theory. Since materiality is also a condition of the state and local False Claims Act analogs under which Bierman has sued, Bierman likewise cannot sustain claims under those statutes.

IV. Conclusion

Accordingly, DJO's Motion for Summary Judgment (Docket # 382) is ALLOWED, and its remaining motions (Docket ## 380 and 384) are DENIED AS MOOT. Given that the other remaining defendants are in the final stages of settlement, see Docket # 408, there is no just reason for delaying judgment for DJO. Judgment may be entered for DJO.

April 11, 2016
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE