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MedTech update 2020 — Legal and regulatory issues to watch for in the medical technology industry in the new year: False Claims Act enforcement

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Medical device and diagnostics companies and laboratories should anticipate significant legal, regulatory and market changes in 2020 that will have a lasting impact on the industry. From revisions to how the government regulates value-based care, to shifts in the marketplace for medtech mergers and acquisitions (M&A), 2020 will prove to be another year of evolution.

Based on recent trends and developments, Akin Gump attorneys have prepared several articles to provide the medtech industry with a landscape overview of the following issues in the year ahead: Food and Drug Administration regulatory developments; federal health care programs; international trade; intellectual property (IP) litigation; False Claims Act enforcement and health information and privacy and data protection.

We plan to monitor and report on these developments and potential updates as the year unfolds.

FALSE CLAIMS ACT ENFORCEMENT

The False Claims Act (FCA) is the government's primary weapon for policing fraud committed against the government.

The FCA's qui tam provisions authorize private citizens, known as "relators," to file lawsuits and obtain a substantial statutory bounty from funds that otherwise would be remitted to the government. Over the last few years, the Department of Justice (DOJ) and relators have specifically targeted medtech companies.

There are three trends in FCA enforcement that are especially important to watch in 2020 for medtech companies:

Continued application of AKS to medtech consulting arrangements.

A primary enforcement mechanism of the AKS is the FCA. There has been an uptick in qui tam cases alleging an AKS violation. One area of scrutiny continues to be medical device and drug manufacturers retaining health care professionals as consultants to educate other health care professionals regarding the benefits of the product.

FCA plaintiffs frequently characterize such payments as kickbacks to induce referrals. In these lawsuits, courts typically evaluate whether, under the facts and circumstances, the payments are for bona fide work or are more fairly characterized as sham payments.[1]

In 2019 the Eleventh Circuit, in *Bingham v. HCA, Inc.,* found that there is no AKS violation if fair market value is paid to the physician.[2]

> If the government pays on the claim and does not seek repayment, this is considered strong evidence that any alleged infraction is not material to the government under the FCA.

An issue to watch in 2020 will be the extent to which other courts adopt *Bingham's* reasoning and that proof, by itself, that payment is set at fair market value will be a dispositive defense regardless of the parties' intent.

FCA materiality defenses will continue to be tested.

Historically, relators have asserted that medtech companies and drug manufacturers committed fraud by failing to report adverse events,[3] producing products with a higher than expected failure rate[4] and failing to adhere to current good manufacturing practices.[5]

For the most part, courts have rejected these theories, finding that qui tam relators should not be permitted to supplant the FDA's expertise regarding what products should be allowed into the market and what remedy should be imposed when a product fails.[6]

The Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar* cemented this line of precedent, noting that in assessing materiality, the court should look at the actual behavior of the government.[7]

If the government pays on the claim and does not seek repayment, this is considered strong evidence that any alleged infraction is not material to the government under the FCA.[8] Post-*Escobar*, courts have expanded this defense.[9]

Both the government and relator have contended that this line of precedent ignores that the agency does not always have all the facts when it continues to approve the product.[10]

An issue to watch in 2020 is whether DOJ and relators will start to have more success in dismantling the strong FCA materiality defense the Supreme Court erected in *Escobar* or seek legislative relief.

Continued challenges to the use of subregulatory guidance as the foundation for an FCA action.

A third trending development is the extent to which alleged violations of subregulatory guidance can result in an FCA violation. Just recently, one district court concluded that substantive legal rules must be issued pursuant to notice and comment rulemaking to serve as a basis to assert FCA liability.

In *Polansky v. Exec. Health Res., Inc.*,[11] the court considered whether subregulatory guidance CMS issued in manuals for hospitals to determine the inpatient status of patients for purposes of seeking reimbursement under the Medicare Act could serve as the basis for determining whether claims are false under the FCA.

The court noted that in light of a recent Supreme Court case[12] and a D.C. Circuit case, *Allina Health Servs. v. Price*,[13] the Medicare Act requires that a substantive legal standard be subject to notice and comment rulemaking.

The district court, after adopting the D.C. Circuit's construction of substantive legal standard as "at a minimum … a standard that creates, defines, and regulates the rights, duties, and powers of parties," concluded that CMS' manual guidance constituted a substantive legal standard "and therefore required notice and comment rulemaking procedures."[14]

Because the guidance at issue in the case was not issued pursuant to notice and comment, the court concluded that there was not a binding rule, and hence there could be no FCA liability.[15]

Because of CMS' and FDA's substantial reliance on subregulatory guidance, how other courts view the district court ruling in *Polansky* will be worth watching in 2020.

Notes

[1] *Compare United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1055 (C.D. Cal. 2016) (granting summary judgment for defendant on the portion of relator's claim related to speaker programs because there was "no evidence that [the defendant] considered the number of prescriptions a doctor had written in deciding whether to employ the doctor as a speaker," "no evidence that speeches were given in unconventional venues or in the absence of bona fide attendees," and no evidence that the defendant tracked the number of prescriptions written by speakers) with *United States v. Teva Pharms. USA, Inc.*, No. 13 Civ. 3702, 2019 WL 1245656, at *9 (S.D.N.Y. Feb. 27, 2019) (noting that in "cases where a company's speaker program is alleged to have violated the AKS, scienter may be established by, among other things, evidence that senior management was 'basing representatives' compensation on doctors' prescription-writing; [] failing to monitor events; and [] imposing no discipline when sales representatives were reported for non-compliance with [the company's] policies and the anti-kickback laws'.... The inference also arises from evidence showing that the company violated its own compliance policies and industry standards") (citation omitted).

[2] *Bingham v. HCA, Inc.*, 783 F. App'x 868, 873 (11th Cir. 2019) (finding that an AKS violation "requires that there be 'remuneration' offered or paid in the transaction at issue" and noting that Black's Law Dictionary defines "remuneration" in pertinent part as "[p]ayment; compensation" and that compensation, in turn, "cannot be given unless some sort of benefit is conferred. See, e.g., Compensation, Black's Law Dictionary (11th ed. 2019) ('Remuneration and other benefits received in return for services rendered')," and thus concluding regarding a lease business transaction like those at issue in the case, "the value of a benefit can only be quantified by reference to its fair market value" and noting that this "understanding of 'remuneration' is supported by the definition of 'remuneration' in 42 U.S.C. § 1320a-7a(i)(6), which relates to civil monetary penalties in connection with medical fraud. Although that definition is limited to that particular section of Title 42, it also defines 'remuneration' to include the 'transfer[] of items or services for free or for other than fair market value' and thus is consistent with our view of the correct definition" and thus "the issue of fair market value is not limited to" defendant's safe harbor defense, "but is rather something Relator must address in order to show that [the defendant] offered or paid remuneration to physician tenants").

[3] *See, e.g., United States ex rel. Ge v. Takeda Pharm. Co.*, No. 10-cv-11043, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012), *aff'd on other grounds*, 737 F.3d 116 (1st Cir. 2013).

[4] *See, e.g., United States ex rel. Ruhe v. Masimo Corp.*, 977 F. Supp. 2d 981, 996 (C.D. Cal. 2013), *aff'd*, 840 F. App'x 666 (9th Cir. 2016).

[5] *See, e.g., United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700-02 (4th Cir. 2014).

[6] *See, e.g., id.* (finding that where the relator contended that defendant violated the FDA's Current Good Manufacturing Practice (CGMPs) regulations, causing drugs to be "adulterated," because penicillin and non-penicillin drugs were not packaged in complete isolation from one another, the relator did not state a cause of action because "compliance with the CGMPs is not required for payment by Medicare and Medicaid" and the "relevant statutes do not provide that when an already-approved drug has been produced or packaged in violation of FDA safety regulations, that particular drug may not be the proper subject of a reimbursement request under Medicare and Medicaid" and thus concluding that "once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations;" finally the court noted that in "the present case, the FDA pursued numerous regulatory actions against [the defendant], including conducting multiple inspections of the Toledo building and issuing the warning letter. The FDA also threatened seizure of [the facility] products, use of injunctive remedies, and action recommending 'disapproval of any new applications listing [the facility] as a manufacturer of drugs.' The existence of these significant remedial powers of the FDA buttresses our conclusion that Congress did not intend that the FCA be used as a regulatory-compliance mechanism in the absence of a false statement or fraudulent conduct directed at the federal government"); *Masimo Corp.*, 977 F. Supp. 2d at 996 (finding that the relators did not establish that the medical devices defendant supplied were worthless because defendant "presented overwhelming evidence of its good faith belief in the medical value of the … Devices as well as their value to members of the medical community" and the "Relators have not shown any genuine dispute regarding the medical value of the … Devices"); *Takeda Pharm. Co.*, 2012 WL 5398564, at *6 (ruling that the legal requirement that drug companies report adverse events is a condition of participation, because the "FDA has discretion

to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements" and thus because the "relator has not adequately established compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6)").

[7] 136 S. Ct. 1989, 2002 (2016).

[8] *Id.* at 2003-04 (if "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that these requirements are not material").

[9] *See, e.g., U.S. ex rel. D'Agostino v. EV3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) ("The FDA's failure actually to withdraw its approval of Onyx in the face of [the relator's] allegations precludes [the relator] from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so. The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings") (citations omitted). *Cf. U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34-35, 40 (1st Cir. 2017) (finding that because of the FDA's failure to apply any administrative sanction in the wake of the relators' allegations, the relators' fraud on the FDA assertions were "implausible" and noting that ruling "otherwise would turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so" but also holding that the relators' non-fraud on the FDA claims that the defendant "palmed off" latently defective versions of its FDA-approved product on unsuspecting doctors who sought government reimbursement to be a viable theory of liability).

[10] *See generally United States ex rel. Campie v. Gilead Scis.*, 862 F.3d 890, 906-07 & n.9 (9th Cir. 2017) (reversing district court dismissal because although defendant set forth factors indicating that the government knew of underlying allegations yet continued to pay, because defendant had stopped engaging in alleged improper practice, the government continuing to pay for drugs did not have the same significance in assessing materiality; additionally, the court noted that the parties disputed what the government actually knew and when and hence the issues raised by the parties were matters of proof and "not legal grounds to dismiss relators' complaint" when at "the pleading stage" the court assumes "the facts alleged by the relators to be true") (citation omitted).

[11] No. 12-cv-4239, 2019 WL 5790061 (E.D. Pa. Nov. 5, 2019).

[12] *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

[13] 863 F.3d 937, 943 (D.C. Cir. 2017).

[14] *See* 2019 WL 5790061, at *14.

[15] *Id.* at *16 ("Since the 24-hour policy was contained in agency manuals that had not been promulgated pursuant to notice and comment, Allina compels the conclusion that there can be no FCA liability on Relator's Phase I claims").

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