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Health Care ADVISORY ■

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Don't Discount the Government's Recent Statement of Interest in False Claims Act Case

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On August 8, 2016, the U.S. government filed a Statement of Interest in an ongoing False Claims Act (FCA)/Anti-Kickback Statute (AKS) case, *U.S. ex rel. Herman v. Coloplast Corp.*, No. 1:11-cv-12131 (D. Mass.). Certain claims in the case turn on whether particular arrangements qualify as "discounts" under the discount exception or safe harbor to the AKS or whether they should instead be viewed as illegal kickbacks. While the government has not intervened in the kickback claims discussed in the Statement of Interest, the document provides insight into the government's current interpretation of the discount exception and safe harbor.

Background

In December 2011, qui tam relators filed suit in the District of Massachusetts against Coloplast A/S and its subsidiary Coloplast Corp, as well as multiple durable medical equipment (DME) manufacturers and suppliers in the ostomy, continence care and wound/skin care industries. The complaint alleged that Coloplast had paid kickbacks to other defendants in a variety of forms, such as "patient conversion bonus payments to sales representatives,""market share 'incentive payments'" and "below-market discounts," in order to induce the defendants to recommend the referral, order and purchase of certain DME products.

The government intervened in certain claims against some of the defendants—i.e., Coloplast, Liberator Medical Supply Inc., Hollister Inc. and Byram Healthcare Suppliers Inc.—all of which ultimately settled those claims with the government. These settlements ranged from $500,000 to $11.5 million. Many of the claims against the defendants (collectively and individually), however, remained live, and the relators filed their third amended complaint in May 2016, alleging additional AKS violations against several of the defendants. Two of these defendants, CCS Medical Inc. and Hollister, filed motions to dismiss in June 2016.

Dismissal of Claims Against CCS

On July 29, 2016, the court granted CCS's motion to dismiss claims against it for allegedly engaging in a kickback scheme with Coloplast. After listing the requirements for the statutory discount exception and the regulatory

discount safe harbor to the AKS,[1] the court concluded that the relators had failed to "allege—and certainly not with the requisite particularity—that Coloplast failed to disclose the discounts to CCS in writing, nor do they allege that Coloplast and CCS enshrined the discounts through oral, collateral, or otherwise off-the-books agreements." Because the court found that the relators had not adequately alleged an AKS violation, it dismissed the AKS claims against CCS as well as the related FCA claims.

U.S. Government's Statement of Interest

After the relators filed a motion for reconsideration of the court's dismissal, the government followed on August 8, 2016, by filing a Statement of Interest regarding the relators' motion. While the government has not intervened against CCS on these claims, it filed this statement in order to "state its position on the confines of the 'discount' exception to the AKS."

Importantly, the government contends that the court mischaracterized the relators' allegations against CCS and, as such, improperly assumed that the price reductions at issue could fall within the discount exception and safe harbor. The court described the allegations as involving "volume-based discounts to suppliers with sufficient market power to move more of its products" and noted that "CCS relied on what relators term 'hard' and 'soft' tactics" to increase sales, but the government argues that this description misrepresented the relators' allegations. In particular, the government underscores the distinction between:

1. A buyer that "independently (not pursuant to an agreement with [the seller]) relied on certain 'hard' or 'soft' sales tactics to achieve the increased sales" under a "pricing structure that offered escalating discounts in return for increased sales."

2. An agreement between a buyer and seller under a similar pricing structure that the buyer would "undertake patient conversion and referral activities in return for [the seller] granting price concessions."

According to the government, the former would constitute a "discount" and, as such, would not violate the AKS, whereas the latter would *not* qualify as a "discount" and thus could violate the AKS.

The following additional excerpts from the Statement of Interest provide further insight into the government's current thinking on the scope and applicability of the discount exception and safe harbor:

- "A discount is a reduction in price conditioned only on the purchase of the product or service at issue. If a reduction in price is conditioned on more than a simple purchase, it is not a mere 'discount,' but rather a form of remuneration whose legitimacy must be evaluated under the anti-kickback statute separate and apart from the statutory discount exception or regulatory discount safe harbor. In other words, *if a price reduction is conditioned on more than the purchase of a product, then it is not a mere discount and it is irrelevant whether that price reduction was 'properly disclosed*.'" (emphasis added)

- "The United States submits that remuneration from a manufacturer to a distributor in return for specific conversion and referral activities – even when the remuneration takes the form of a price concession – is not a 'discount.' Rather, it is illegal remuneration for conduct or services intended to convert patients to the manufacturer's product. … Such an arrangement is different in kind from merely offering escalating discounts in return for increased sales volumes in an [arm's-length] transaction. The collusive quality of the arrangement

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[1] 42 U.S.C. § 1320a-7b(b)(3)(A); 42 C.F.R. § 1001.952(h).

alleged by the relators fundamentally distorts the transparency of price competition in the healthcare market that Congress sought to promote with the discount exception."

- "In sum, a price reduction conditioned on promotional or conversion campaign activities is not a 'discount' within the meaning of the discount exception at 42 U.S.C. § 1320a-7b(b)(3). A price reduction that is contingent on the recipient taking affirmative steps to generate additional business for the seller does not foster price competition that inures to the benefits of the federal health care system."

Other Recent Cases

The government's Statement of Interest also references a few prior District of Massachusetts cases in support of its views that the discount exception and safe harbor are narrow;[2] merely labeling something a "discount" or "rebate" does not guarantee protection under the discount exception or safe harbor since the *intent* of the arrangement is central to compliance with the AKS;[3] and agreements involving potential "conversion" or "switching" may receive heightened scrutiny.[4] Recent cases in other jurisdictions have similarly suggested close attention to pricing arrangements involving alleged "swapping," "switching," or "dangling." In Statements of Interest in other cases, the government has also expressed similar concerns about payments "in return for efforts to switch patients to the [seller's products] and increase utilization," and has emphasized that the government does not view such payments as "discounts" for purposes of the discount exception or safe harbor.

Conclusion

As this case demonstrates, the government is taking an extreme position regarding application of the discount safe harbor, trying to strictly limit its applicability to the most basic and simplistic price reductions. Fortunately, the court in this case has (at least so far) taken an expansive view that is more consistent with Congress's explicit policy in favor of discounts and properly disclosed pricing arrangements that benefit government payors. To imply that any price reduction also involving preferred positioning, exclusivity, marketing or promotional activities could be per se illegal is not only aggressive, it goes well beyond existing guidance.

Regardless of how the court ultimately rules, the Statement of Interest is a troubling indicator of the government's position on the enforcement of pricing arrangements in the health care arena. Given this environment, health care providers, manufacturers and distributors should remain aware of ongoing developments and seek experienced legal counsel to review proposed discounting arrangements.

Please do not hesitate to contact us if you have any questions or concerns about the material discussed above or if you would like assistance evaluating or structuring your purchasing and sales arrangements involving discounts related to the requirements of the discount exception and safe harbor to the AKS.

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2 *U.S. ex rel. Banigan v. Organon USA, Inc.*, 883 F.Supp. 2d 277, 296 (D. Mass. 2012) (describing the regulatory definition of "discount" as "exhaustive").

3 *U.S. v. Shaw,* 106 F.Supp. 2d 103 (D. Mass. 2000).

4 *Lisitza v. Johnson & Johnson*, 765 F.Supp. 2d 112 (D. Mass. 2011).

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