UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA and THE STATE OF CALIFORNIA *ex rel.* KIMBERLY HERMAN, AMY LESTAGE, and KEVIN ROSEFF,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 11-12131-RWZ
COLOPLAST CORP., *et al.*,	)	
Defendants.	)	

UNITED STATES' STATEMENT OF INTEREST REGARDING DEFENDANT CCS MEDICAL, INC.'S MOTION FOR RECONSIDERATION OF THE COURT'S AUGUST 24, 2016, ORDER OR TO CERTIFY THE MATTER FOR INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

The United States submits this brief to supplement its prior Statement of Interest (ECF No. 170) concerning the "discount" exception to the anti-kickback statute ("AKS"), and to respond to CCS's interpretation of the Supreme Court's decision in *Universal Health Services v. U.S. ex rel. Escobar*, 579 U.S. ___, 136 S. Ct. 1989 (2016).

ARGUMENT

A. The Alleged Arrangement Between CCS And Coloplast Corp. Is Not A "Discount."

On reconsideration, the Court properly denied CCS's motion to dismiss and should also deny CCS's new motion because the plain language of the AKS and pertinent regulations and guidance from the United States Department of Health and Human Services, Office of Inspector General ("HHS-OIG") do not support CCS's arguments.

A discount is a reduction in price and nothing more. 42 U.S.C. § 1320a-7b(b)(3)(A); *see also* 42 C.F.R. § 1001.952(h)(5) (defining discount to be a "reduction in the amount a buyer

(who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction."). Inherently, a discount is a reduction in price contingent on a purchase by the customer. If, however, the reduction in price is contingent on the customer taking action beyond a purchase (*e.g.*, recommending that others purchase or prescribe the product), that is more than a discount, and must be analyzed accordingly.

HHS-OIG's discount safe harbor explains that discounts do not include any arrangement not "explicitly described" within it. 42 C.F.R. § 1001.952(h)(5); *see also* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (May 5, 2003) (explaining that the discount exception "covers only reductions in the product's price").[1] The safe harbor regulation never suggests that it would apply to a reduction in price given in exchange for services such as the promotional services that the relators allege CCS performed for Coloplast. This strict interpretation of "discount" makes sense, because the statutory and regulatory treatment of discounts exists only to protect true discounts that can create price competition and "result[] in savings to [M]edicare and [M]edicaid program costs." H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056; *see also United States v.*

[1] There is no merit to the argument of the Pharmaceutical Research and Manufacturers of America ("PhRMA") that due process principles and the rule of lenity dictate a different interpretation of the discount exception. The definition of a discount is set forth in the plain and clear language of the AKS, the regulations, and HHS-OIG guidance, sufficient to put CSS and Coloplast on notice of the parameters of the safe harbor. *See United States ex rel. Banignan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 296 (D. Mass. 2012); *see also United States v. Flores-Rivera*, 787 F.3d 1, 25 (1st Cir. 2015) (Rule of lenity "only applies if there is a grievous ambiguity in the statute") (quoting *United States v. Jimenez*, 507 F.3d 13, 21 (1st Cir. 2007). In any event, any concerns about fair notice and due process are appropriately addressed through rigorous application of the scienter requirements of the AKS and the FCA and the materiality requirement of the FCA. *See Escobar*, 136 S. Ct. at 2002. Whether CCS acted "knowingly and willfully" cannot be resolved as a matter of law at the pleading stage of the case.

Shaw, 106 F. Supp. 2d 103, 111 (D. Mass. 2000). Remuneration from a manufacturer to a distributor in return for specific personal services, such as conversion and referral activities, does not create price competition; rather, it encourages collusive arrangements that fundamentally distort the market incentives that Congress sought to promote with the discount exception. *See Shaw*, 106 F. Supp. 2d at 116 ("Discounts were only transactions made on an arms-length basis and not through a joint-venture or collusive contract.") (citing 56 Fed. Reg. 35,952, 35,977 (1991)).

To be sure, a manufacturer like Coloplast can engage a distributor like CCS to perform advertising and promotional services. There is a safe harbor for such personal service and management arrangements, 42 C.F.R. § 1001.952(d), but such arrangements must, among other things, be based on fair market value for the services without regard for the volume of sales or business generated by the arrangement, 42 C.F.R. § 1001.952(d)(5). Nothing in the AKS or HHS-OIG regulations suggests that a manufacturer and a distributor can hide a personal services contract within a discount, particularly a discount based on volume or market share. Were such an arrangement found to be permissible, the discount safe harbor would swallow many, if not all, of the other safe harbors.

In sum, the United States submits that the Court correctly denied CCS's motion to dismiss and should deny CCS's motion to reconsider—not because CCS's alleged arrangement with Coloplast failed to comport with the formalities of the discount safe harbor, 42 C.F.R. § 1001.952(h)(1)(iii),[2] but rather because the alleged arrangement between Coloplast and CCS is not a "discount" at all.

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[2] The safe harbor at 42 C.F.R. § 1001.952(h) includes a number of requirements with respect to discounts, which vary depending on the type of buyer. With respect to a buyer who submits a claim to a Federal health care program, the requirements include that the seller of an item or

B. CCS's Invocation Of *Escobar* Is Mistaken.

CCS incorrectly argues that relators seek recovery under an "implied false certification" theory and that the Supreme Court's recent decision in *Escobar* somehow forecloses the relators' action. *Escobar* addressed whether and under what circumstances the implied false certification theory can establish a basis for FCA liability. 136 S. Ct. at 1999-2001. This case, however, does not implicate the implied false certification theory, because Congress has decreed, in the plain language of the AKS, that any claim that results from a kickback is a false claim for purposes of the FCA. 42 U.S.C. § 1320a-7b(g).[3] By explicitly linking the AKS and the FCA, Congress effectively bypassed any issue about the implied false certification theory in a kickback case like this one.

CCS's invocation of implied false certification theory may stem from the First Circuit's decision in *United States ex rel. Hutcheson v. Blackstone Medical, Inc*., 647 F.3d 377, 385-87

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service fully and accurately report the discount on the invoice, coupon, or statement submitted to the buyer and that the buyer provide such information to the Secretary of Health and Human Services or a State agency upon request. Thus, if the Secretary or a State agency requests disclosure, the buyer must provide the requested information to retain protection under the safe harbor. If, however, the Secretary or a State agency has not requested disclosure, safe harbor protection remains available if all other requirements are met. One of those requirements, of course, is that that the arrangement qualify as a "discount" in the first place. Because the alleged arrangement between CCS and Coloplast is not a discount, the specific requirements of the discount safe harbor are irrelevant.

[3] Section 1320a-7b(g) provides:

> In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.

This provision was added by the Patient Protection and Affordable Care Act, Pub.L. No. 111–148, § 6402(f), 124 Stat. 119, 759 (2010). It applies to the relators' claims against CCS, the time period for which is alleged to begin in 2010.

(1st Cir. 2011), in which the First Circuit considered whether a violation of the AKS would give rise to FCA liability under the implied false certification theory. But the court undertook that analysis only because the complaint in *Hutcheson* was filed before the 2010 amendment to the AKS that added section 1320a-7b(g). *See* 647 F.3d at 380 & n.3. Here, section 13020a-7b(g) is clearly applicable. Under the current law, if CCS submitted claims that included items resulting from a violation of the AKS, such claims were unquestionably "false."

Even if this Court were inclined to view relator's claim against CCS as a form of implied certification claim, CCS misinterprets *Escobar* as establishing an absolute requirement that implied false certification liability can attach *only* when two specific conditions are met. The Court in *Escobar* stated that an implied certification cause of action can be pursued "at least" where (1) the claim makes "specific representations about the goods or services provided," and (2) the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths. *See* 136 S. Ct. at 2001. However, the Supreme Court expressly declined to "resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment." *See* 136 S. Ct. at *2000. It thus left intact the law of this Circuit in *Hutcheson* that claims seeking funds for which the defendant is ineligible because the defendant violated a material payment requirement are false claims under the FCA. As noted, where the violation involves the AKS, the conclusion that the defendant has submitted a false claim is bolstered by the express language of PPACA.[4]

[4] While its brief is somewhat unclear, CCS only appears to dispute the element of falsity and does not argue that materiality (as construed by *Escobar*) is lacking as a matter of law. To the extent CCS raises that issue, there can be no serious dispute that materiality has been adequately alleged here, in light of the explicit statutory language, the clear importance of patients receiving products based on medical need and not a supplier or manufacturer's financial interest, and the government's long history of enforcement actions. *See also United States ex rel. Rose v.*

CCS's erroneous argument that *Escobar* has set forth the maximum contours of implied certification liability is nearly identical to that made and rejected in *United States ex rel. Rose v. Stephens Institute,* 2016 WL 5076214, at *2, 5 (N.D. Cal. Sept. 20, 2016). The court's analysis in that case is correct:

> The language in Escobar that AAU relies upon does not purport to set out, as an absolute requirement, that implied false certification liability can attach only when these two conditions are met.

Id. at *5. Similarly, the First Circuit's prior holdings that claims are false if a defendant seeks money while in violation of a material payment requirement remains good law following *Escobar*, and for this reason as well, CCS's falsity challenge should be rejected.

Respectfully submitted,

Dated: October 6, 2016

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Stephens Institute, 2016 WL 5076214 at *6 (agency's corrective actions, fines, and settlement agreements demonstrated materiality of violation).

Certificate of Service

I hereby certify that on this 6th day of October, 2016, the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants.

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