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 PLAINTIFF'S MOTION FOR RECONSIDERATION OF THE COURT'S DISMISSAL OF CCS

I. INTRODUCTION

The United States, as the real party-plaintiff in interest in this action, submits this Statement of Interest pursuant to 28 U.S.C. § 517, with respect to Plaintiffs' Motion ror Reconsideration of the Court's Dismissal of CCS (Dkt #166). Because the UnitedStates remains the real party in interest even where it has not intervened in an action, *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004),[1] and because the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, is the United States' primary tool in prosecuting

[1] The United States notes in this regard that its decision to decline intervention as to CCS Medical cannot be taken as a statement on the underlying merits of relators' claims. "Because the government 'may have a host of reasons for not pursuing a claim,' courts 'do not assume that in each instance in which the government declines intervention in a[] F[alse] C[laims] A[ct] case, it does so because it considers the evidence of wrongdoing insufficient or the *qui tam* relator's allegations [of] fraud to be without merit.'" *United States ex rel. Feldman v. Van Gorp*, No. 03 Civ. 8165 (WHP), 2010 WL 2911606 (S.D.N.Y. Jul. 8, 2010) (quoting *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n. 17 (11th Cir. 2006)). Indeed, "the plain language of the Act clearly anticipates that even after the Attorney General has 'diligently' investigated a violation [of the False Claims Act], the Government will not necessarily pursue all meritorious claims." *United States ex rel. Berge v. Bd. of Trustees*, 104 F.3d 1453, 1458 (4th Cir. 1997) (internal citations omitted).

fraud on the government, the government has a substantial interest in the development of the law in this area and in the correct application of that law in this, and similar, cases. The United States submits this brief to state its position on the confines of the "discount" exception to the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(3)(A) (2012).

II. ARGUMENT

A. A Price Reduction Conditioned On the Performance of Promotional or Conversion Campaign Activities Is Not a "Discount" Under 42 U.S.C. § 1320a-7b(b)(3)

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."

In their Third Amended Complaint (Dkt # 121), the relators make allegations that, if proven, would show that CCS accepted remuneration from Coloplast in the form of price reductions that would not qualify as discounts under the discount exception or safe harbor. They allege that "CCS accepted hundreds of thousands of dollars in price reductions and discounts from Coloplast in exchange for conducting conversion and marketing campaigns to induce patients to try Coloplast Products or to switch from a competitor's ostomy and/or continence care products to Coloplast-brand Products." 3d Am. Compl. ¶ 91. Relators give two examples. First, "in 2011 Coloplast agreed to give CCS a price reduction on Coloplast's SpeediCath urological catheter product in return for CCS undertaking a promotional campaign to convert CCS

customers to the Coloplast product." *Id*. ¶ 92. Second, "in late 2012, Coloplast agreed to reduce its prices for ostomy products in return for CCS engaging in 'hard conversion' campaigns of patients (i.e. patients were told that they could no longer order the competitor products through CCS)." *Id*. ¶ 93.

The Court, in its Opinion and Order dated July 29, 2016 (Dkt #162), describes the relevant conduct somewhat differently and assumes that the price reductions at issue were discounts that could qualify for protection under the discount exception and safe harbor:

> Coloplast purportedly offers volume-based discounts to suppliers with sufficient market power to move more of its products. Having identified CCS as such a supplier, Coloplast approached the company as a potential partner, offering escalating discounts in exchange for increased sales at some point in 2011. To boost sales, CCS relied on what relators term "hard" and "soft" tactics: under the hard approach, CCS simply lied to patients about the availability of other brands' products; under the soft approach, CCS or Coloplast would contact patients to persuade them to switch.

Id. at 3.

In the United States' view, there is a critical difference between the relators' allegations and the Court's description. If CCS and Coloplast simply agreed to a pricing structure that offered escalating discounts in return for increased sales, and CCS then independently (not pursuant to an agreement with Coloplast) relied on certain "hard" and "soft" sales tactics to achieve the increased sales, then the United States agrees that such an arrangement would qualify as a "discount" and therefore would not violate the AKS. In contrast, if CCS and Coloplast agreed that CCS would undertake patient conversion and referral activities in return for Coloplast granting price concessions, the United States submits that such an agreement would not be a "discount" at all and would violate the AKS.

Congress passed the anti-kickback statute to address "practices which have long been

regarded by professional organizations as unethical . . . and which contribute appreciably to the cost of the [M]edicare and [M]edicaid programs." H.R. Rep. No. 92-231, at 104 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093; *see also United States v. Ruttenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980) (observing that "kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed"). To protect the Medicare and Medicaid programs from such practices, the anti-kickback statute prohibits any entity, such as CCS, from knowingly and willfully soliciting or receiving any remuneration "in return for . . . recommending purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program," 42 U.S.C. §1320a-7b(b)(1), and it prohibits any entity, such as Coloplast, from knowingly and willfully offering or paying any remuneration to induce another entity "to purchase . . . or recommend purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

At the same time, Congress recognized that discounts often are "a good business practice which results 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. Shaw*, 106 F. Supp. 2d 103, 111 (D. Mass. 2000). Accordingly, Congress created an exception to the anti-kickback statute for a "discount or other reduction in price." 42 U.S.C. § 1320a-7b(b)(3)(A). In guidance to the pharmaceutical industry, the HHS Office of Inspector General ("HHS-OIG") has made clear that this exception is narrow and "covers only reductions in the product's price." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (May 5, 2003). *And see United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp.

2d 277, 296 (D. Mass. 2012) (noting that the regulatory definition of "discount" at 42 C.F.R. § 1001.952(h)(5) is "exhaustive," and citing 42 C.F.R. § 1001.952(h)(5)(vii) (the term "discount" does not include "other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section")). Remuneration to health care providers for switching patients from one product to another, and for other efforts to increase a product's utilization do not qualify as protected price reductions, even if the parties label the remuneration as "rebates" or "discounts."

In declining to dismiss a criminal indictment based on the defendant's assertion of the discount exception, the district court in *Shaw* concluded, "All of these cases confirm that the issue for a jury to decide, when faced with a defendant whose contention is that the defendant is not criminally liable under the statute due to the 'discount exception,' is whether the reason for offering or accepting the 'discount or other reduction in price' was to induce referrals of or be reimbursed for federal health care business." *Shaw*, 106 F. Supp. 2d at 121. The defendant in *Shaw* was alleged to have offered special pricing or rebates "in exchange for receiving referrals" for laboratory testing for Medicare patients. *Id.* at 107.

In *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F.Supp.2d 112 (D. Mass. 2011), the government alleged that Johnson & Johnson ("J&J") paid kickbacks to Omnicare, Inc. to induce Omnicare to purchase a J&J drug. One of the kickback schemes consisted of two agreements under which Omnicare received rebates on the purchase price of a J&J drug if (a) Omnicare's purchases met a threshold share of the market, and (b) Omnicare successfully implemented two programs designed to shift market share (*i.e.*, switch patients) to the J&J drug. *Id.* at 117. J&J moved to dismiss the complaint, arguing in part that the rebates fell within the discount exception. *Id*. at 124-125. The court disagreed, observing that "Omnicare qualified for a rebate on a specified drug only if its purchases of the drug from J&J met market share

thresholds at the expense of J&J's competitors, and only if it succeeded in implementing the 'Active Intervention' and 'Appropriate Use' Programs with its pharmacists." *Id.* at 125.

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. The products at issue in this case, ostomy and continence care products, are typically sold to patients with chronic or life-long medical needs, and switching a patient to a particular brand, such as Coloplast sought to do, can mean a steady stream of revenue for many years. The conversion campaigns that Coloplast allegedly financed had significant value to Coloplast, as they could establish brand loyalty well beyond the duration of the pricing arrangement with CCS. Relators' allegations carry a reasonable inference that Coloplast was paying CCS to use its special influence with its customers to switch them to the Coloplast products. [2] As alleged, CCS's agreement to undertake conversion campaigns in exchange for the price concessions thus transformed the price concessions into illegal kickbacks. Such an arrangement is different in kind from merely offering escalating discounts in return for increased sales volumes in an arms-length transaction. The collusive quality of the arrangement alleged by the relators fundamentally distorts the transparency of price competition in the healthcare market 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)) .

[2] *C.f.* 42 C.F.R. § 1001.952(h)(5)(vi) ("safe harbor" regulation of Office of Inspector General, Health and Human Services, defining "discount" as not including "Services provided in accordance with a personal or management services contract").

In a 1994 Special Fraud Alert, the HHS OIG made clear its view that the AKS prohibits manufacturers from offering financial incentives to those selling their products to effectuate "product conversion" programs where one purpose is to induce the increase use of such products covered by Federal health care programs. 59 Fed. Reg. 65,371, 65,372, 65,376 (Dec. 19, 1994). One of the examples provided in the Special Fraud Alert was of a "product conversion" program in which a drug manufacturer provided supplier pharmacies with cash awards for changing from a competitor's product to the drug manufacturer's product. *Id*. at 65,376. A price concession is functionally no different than such a cash award, regardless of the label the parties use to describe it.

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.

B. If the Court Concludes the Relators Have Failed to Plead Their Claims Against CCS With Sufficient Specificity, Any Dismissal Should Be Without Prejudice to the United States.

Under the False Claims Act, a relator files his complaint on behalf of the United States, and, once the United States has notified the court that it declines to pursue relator's allegations, relator is free to pursue them on her own. 31 U.S.C. § 3730. Under such circumstances, the United States neither files the complaint that initiated the action nor serves it on defendants. Because the United States has no part in preparing such complaints, it should not be prejudiced if a relator has failed to plead his or her allegations sufficiently. Such a dismissal does not constitute a ruling on the merits of defendants' conduct and does not mean that a better informed

relator or the United States could not make out a viable claim in the future. Moreover, a dismissal with prejudice would be unfair because a relator's complaint that is broadly drafted, if dismissed with prejudice as to the United States, could improperly be argued by a defendant to have the preclusive effect of preventing future actions by the United States against the defendant for conduct that the United States did not investigate and did not know was part of relator's action. This is not in accord with the purpose of the False Claims Act *qui tam* provisions, which is assisting the United States in pursuing fraud, not hindering it, and should not be the result of the dismissal of an improperly pleaded complaint or a disqualified relator, whom the United States does not control. *See United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005) (holding that dismissal with prejudice as to the United States was improper where basis for dismissal was failure to meet heightened pleading standard under Fed. R. Civ. P. 9(b)). Accordingly, the United States submits that, if granted, a dismissal based on the sufficiency of relators' Third Amended Complaint should be without prejudice to the United States.

Dated: August 8, 2016

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