UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, and the STATE OF CALIFORNIA, *ex rel.* KIMBERLY HERMAN, AMY LESTAGE, AND KEVIN ROSEFF, Plaintiffs, v. COLOPLAST CORP., *et al.* Defendants.	Civil Action No. 1:11-cv-12131-RWZ

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF DEFENDANT CCS MEDICAL SUPPLIES, INC.'S MOTION TO RECONSIDER THE COURT'S AUGUST 24, 2016 ORDER OR TO CERTIFY THE MATTER FOR INTERLOCUTORY APPEAL

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, non-profit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that help patients lead longer, healthier, and more productive lives. In 2015 alone, PhRMA's members invested an estimated $58.8 billion in efforts to discover and develop new medicines.[1] PhRMA frequently files *amicus curiae* briefs in cases raising matters of significance to its members.

PhRMA has a substantial interest in ensuring that the legal standards governing the pharmaceutical industry are stable, predictable, and consistent with sound public policy. This False Claims Act ("FCA") case raises important issues of interest to PhRMA members, which regularly enter into discount arrangements with the understanding that those arrangements are protected under the statutory discount exception to the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(3)(A), and the regulatory discount safe harbor adopted by the Department of Health and Human Services Office of Inspector General ("OIG"), 42 C.F.R. § 1001.952(h)(5). PhRMA has an interest in ensuring that, in accordance with the AKS, OIG regulations, congressional intent, and sound public policy, discount arrangements are protected against the threat of AKS or FCA enforcement.

Moreover, PhRMA's members have a strong interest in ensuring that the AKS, either independently or through the FCA, is implemented consistent with its terms as well as with fundamental due process principles of fair notice and an opportunity to be heard. The Government's August 8, 2016 Statement of Interest ("SOI") in this case presented interpretations

[1] Pharmaceutical Research and Manufacturers of America, *2016 Biopharmaceutical Research Industry Profile* (2016), *available at* http://phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

of the discount exception and the discount safe harbor that appear nowhere in the AKS or any OIG regulation. As such, the interpretations amount to "regulation by litigation," raising serious constitutional questions. The Government's interpretations, moreover, threaten criminal and quasi-criminal liability under the AKS and FCA for beneficial discount arrangements that Congress and the OIG sought to protect. The Court's August 24, 2016 Order is predicated on this same misunderstanding of the discount exception and discount safe harbor. PhRMA's members have a profound interest in the proper, consistent, and fair enforcement of criminal statutes that apply to them.

INTRODUCTION

Discounts reduce costs and promote competition. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Recognizing that price competition in the health care sector should be encouraged, Congress long ago carved out "discount[s] or other reduction[s] in price" from the payments prohibited by the AKS. 42 U.S.C. § 1320a-7b(b)(3)(A). Through a regulatory safe harbor last modified in 1999, the OIG reaffirmed that discounts (including rebates) fall outside the AKS's reach so long as, in relevant part, they are "fixed and disclosed in writing to the buyer at the time of the initial sale," and the buyer furnishes documentation, "upon request by the Secretary [of Health and Human Services] or a State agency," of the discount and the buyer's awareness of the obligation to report it. 42 C.F.R. § 1001.952(h).

This Court's July 29, 2016 Opinion and Order correctly dismissed the claims against defendant CCS Medical Supplies, Inc. ("CCS"), because the payment arrangement alleged in relators' Third Amended Complaint ("TAC") falls squarely within the AKS discount exception and the regulatory discount safe harbor. Thereafter, in words that appear nowhere in the discount safe harbor or the AKS itself, the Government's August 8, 2016 SOI argued that "if

CCS and Coloplast [Corp. ("Coloplast")] agreed that CCS would undertake patient conversion and referral activities in return for Coloplast granting price concessions, . . . such an agreement would not be a 'discount' at all and would violate the AKS." SOI at 3. The Court on August 24, 2016 then reconsidered and reversed its dismissal order, concluding that the discount safe harbor does not apply because the TAC does not allege that "CCS has provided certain information concerning the discounts to a governmental agency pursuant to its request." Dkt. #181 at 3.

PhRMA fully agrees with CCS that the Court's August 24, 2016 decision denying dismissal should be reconsidered. As CCS explains, the OIG's discount safe harbor requires a buyer to provide information about a discount *only* "upon request" by the government. CCS Mot. to Reconsider at 3-5. In addition, the interpretation set forth in the Government's SOI and adopted by the Court raises serious constitutional problems. Due process considerations prohibit the Government from adding new terms to the safe harbor—or from carving out certain types of discount arrangements from the safe harbor—in a litigation brief when the defendants did not have advance notice of the Government's position and an opportunity to respond. *See, e.g., Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2168 (2012). PhRMA submits that this Court can and should avoid this constitutional question by reverting to its prior decision dismissing the claims against CCS.[2]

If the Court does not reconsider, PhRMA submits that the proper interpretation of the discount exception and safe harbor is an exceptionally important legal issue that warrants interlocutory appellate review. The Government's SOI and the Court's August 24, 2016 reconsideration decision threaten criminal and quasi-criminal liability under the AKS and FCA respectively for beneficial discount arrangements regularly used by pharmaceutical

[2] This brief focuses only on the proper interpretation of the discount exception and safe harbor, and does not address other issues raised in CCS's motion.

manufacturers. The issue presented is a purely legal one that is dispositive of the claims against CCS in this case, and the Court's interpretation of the safe harbor could have broader implications for discount arrangements that are ubiquitous within the health care sector. Appellate review at this time would materially advance the ultimate termination of this case, and the fact that this Court initially granted dismissal and then reconsidered demonstrates that there is substantial ground for disagreement. Interlocutory review of this important legal question is therefore appropriate.

FACTUAL BACKGROUND

A. Relators' Claims

Relators Kimberley Herman, Amy Lestage, and Kevin Roseff filed this AKS suit against manufacturers and suppliers of ostomy and continence care products, including Coloplast and CCS. According to the relators' Third Amended Complaint, filed May 20, 2016, the defendants allegedly engaged in "illegal kickback schemes, illegal telephone solicitation campaigns, and deceptive sales campaigns designed to defraud Medicare and . . . Medicaid." TAC ¶ 2 (Dkt. #121). For example, the relators alleged that Coloplast, a manufacturer of the ostomy and continence care products at issue, provided kickbacks to CCS, a supplier of the products, in exchange for CCS's "soft campaigning" to move patients to Coloplast products. TAC ¶ 3. The TAC alleges that, as a result of these schemes, CCS "knowingly submitted false claims to Federal health care programs." *Id.*

CCS moved to dismiss for failure to state a claim on the ground that "discount pricing alone, without allegations of concealment, sham agreements, or other wrongdoing is not a violation of the AKS." MTD at 1 (Dkt. #139). On July 29, 2016, this Court granted the motion to dismiss because, based on the TAC paragraphs describing the negotiation record between Coloplast and CCS that preceded the sale of the items in question, the discounts offered were

fixed at the time of the initial sale. Op. at 7 (Dkt. #162). The Court held that the relators did not allege with requisite particularity that Coloplast had failed to disclose the discounts to CCS in writing or that the arrangement was oral or off-the-books. *Id.*

On August 3, 2016, relators filed a motion for reconsideration of the Court's dismissal order. Dkt. #166. There, the relators argued that the TAC adequately pled that Coloplast offered CCS price reductions and discounts in order to induce CCS to convert patients to Coloplast's products. Mot. at 1-2. The relators asserted that, because there supposedly was a "quid pro quo" regarding patient conversion and not just a discount to increase sales, the arrangement violates the AKS. *Id.* at 1. Relators also contended that it is not their burden to rebut the claim that the statutory exception and regulatory safe harbor for discounts apply. *Id.* at 3. They cited *United States ex rel. Banigan v. Organon USA Inc.* and *United States ex rel. Lisitza v. Johnson & Johnson* to assert that, even if the form of a transaction is a discount, the underlying purpose of the transaction can render an activity an unlawful kickback. Mot. at 4-5.

B. The Government's Statement of Interest

On August 8, 2016, the Government, which had previously declined to intervene in this case, filed an SOI setting forth an interpretation of the discount safe harbor. Dkt. #170. In arguing that the statutory exception and regulatory safe harbor for discounts should not apply here, the Government advocated for a distinction between "mere 'discount[s]'" and other "reduction[s] in price" that does not appear in any OIG pronouncements. The SOI in particular asserted as follows:

> 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 AKS 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."

SOI at 2.

According to the Government's SOI, some reductions in price apparently qualify as discounts for purposes of the discount exception and safe harbor, but others do not. The SOI asserted:

> 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.

SOI at 3.

The Government did not cite any statute, legislative history, or regulation for this distinction. Nor did the Government explain how such a rule could work in practice. Instead, the Government relied primarily on an OIG Special Fraud Alert from 1994, which it interprets to mean that discounts contingent on product conversion constitute kickbacks. *See* SOI at 4-7. But a close look at the Special Fraud Alert shows that it does not support the Government's litigation position. Although the alert cautions against product conversion programs, the actual language is as follows:

> Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, *unless the payment is made fully consistent with a 'safe harbor' regulation*, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices (emphasis added).

59 Fed. Reg. 65,371, 65,372, 65,376 (Dec. 19, 1994). As the highlighted language underscores, the Special Fraud Alert actually says that conversion programs can be structured within a safe harbor to the AKS. The alert thus not only does not support the Government's current position, it actually undercuts it. The alert informs companies such as Coloplast and CCS that such programs can satisfy the requirements of a safe harbor, including the discount safe harbor, if structured consistent with the safe harbor's requirements.[3] It certainly does not provide clear notice that the programs at issue here cannot be structured within the discount safe harbor.

C. The Court's August 24, 2016 Order Granting Reconsideration

On August 24, 2016, the Court granted reconsideration and reversed its earlier order dismissing the claims against CCS based on the AKS discount exception and regulatory discount safe harbor. Dkt. #181. Based in part on the Government's SOI, the Court concluded that it previously had "misconstrued the AKS," and that the arrangement alleged in the TAC does not fall within the discount safe harbor unless "CCS has provided certain information concerning the discounts to a governmental agency pursuant to its request." *Id.* at 1, 3. Because the TAC does not allege that CCS provided such information, the Court found that its prior dismissal ruling was "a mistake." *Id.* at 3.

[3] The Government also cited the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,738 (May 5, 2003). But that guidance simply refers back to the 1994 Special Fraud Alert cautioning against "switching arrangements." Moreover, the guidance does not affirmatively reject switching arrangements, but instead provides that the "activity clearly implicates the [AKS], and, while such programs may be permissible in certain managed care arrangements, manufacturers should review very carefully any marketing practices utilizing switching payments in connection with products reimbursable by federal healthcare programs." *Id.*

ARGUMENT

I. This Court Should Reconsider Its Decision Denying CCS's Motion to Dismiss

The AKS prohibits a person from knowingly and willfully offering or paying "remuneration" to any person to induce that person to purchase, prescribe, or recommend items or services payable under a Federal health care program.[4] 42 U.S.C. § 1320a-7b(b)(2). In isolation, that statutory provision could unwittingly criminalize many practices in the health care field that are commonplace and socially valuable, such as discount programs and other cost-saving mechanisms. To prevent this unintended consequence, Congress carved out certain beneficial conduct from the statute's reach.

Among the statutory exceptions, the AKS "shall not apply to a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." *Id.* § 1320a-7b(b)(3)(A). Congress enacted this discount exception "to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal" under the AKS. *See, e.g.*, S. Rep. No. 95-453, at 12 (1977). This language is clear and unambiguous: if a discount arrangement is "properly disclosed and appropriately reflected" in charges made by a seller to a buyer, the discount does not violate the AKS.

Out of concern that, despite the statutory exceptions, the broad language of the AKS, a criminal statute, still "created uncertainty among health-care providers as to which commercial arrangements are legitimate, and which are proscribed," S. Rep. No. 100-109, at 27 (1987), Congress in 1987 directed the OIG to issue regulations establishing additional safe harbors for

[4] The definition of "Federal health-care program" (42 U.S.C. § 1320a-7b(f)) encompasses a number of different programs, but Medicare and Medicaid are the best known.

conduct that would be shielded from prosecution under the AKS. 42 U.S.C. § 1320a-7b(b)(3)(E); Pub. L. No. 100-93, § 14(a), 101 Stat 680 (1987). The OIG thus adopted numerous safe harbors, including one protecting discount arrangements. 42 C.F.R. § 1001.952(h). The OIG explained that the discount safe harbor, "[c]onsistent with the intent of the statute, [was] designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy." 56 Fed. Reg. 35,952, 35,983 (Jul. 29, 1991). The discount safe harbor by its terms protects any "discount," which is defined as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction," 42 C.F.R. § 1001.952(h)(5), and protects buyers, sellers, and offerors (*i.e.* individuals who are not sellers but nevertheless promote purchases at a reduced payment) that meet various requirements regarding disclosure. *See id.* § 1001.952(h)(1)-(3).

The safe harbor and statutory exception for discounts are two separate and distinct bases for protecting arrangements that would otherwise implicate the AKS. Indeed, the statute directing OIG to develop the AKS harbors mandated that "[a]ny practices specified in [the] regulations . . . shall be *in addition to* the practices described in subparagraphs (A) through (C) of [Social Security Act ("SSA")] section 1128B(b)(3)." *See* Pub. L. No. 100-93, § 14(a), 101 Stat 680 (1987) (emphasis added); *accord,* H. R. Rep. No. 104-736, at 245 (1996) ("The 1987 law . . . established authority for the Secretary to promulgate regulations specifying *additional* payment practices, known as 'safe harbors,' which will not be subject to sanctions under the fraud and abuse provisions.") (emphasis added). For this reason, a prior decision in this district cited by the Government (SOI at 5) concluded that the statutory discount provision and the regulatory safe-harbor "are separate and independent bases for which certain activities may be excluded from criminal liability under the anti-kickback statute." *United States v. Shaw*, 106 F.

Supp. 2d 103, 108 (D. Mass. 2000). A discount arrangement is shielded from liability if it falls under *either* the statutory exception or the regulatory safe harbor.

The arrangements alleged in the TAC fit squarely within both the discount statutory exception and the regulatory discount safe harbor. The statutory exception by its terms applies to "a discount or other reduction in price" without limitation as to the types of discounts that are covered. 42 U.S.C. § 1320a-7b(b)(3)(A) (emphasis added); *see Baez v. INS*, 41 F.3d 19, 24 (1st Cir. 1994), *cert. denied*, 515 U.S. 1158 (1995) (attributing ordinary usage to words in a statute that are not defined). The exception encompasses all discounts, whether linked to market share, volume, or formulary requirements. Furthermore, the Government's main argument—that there is a distinction between "discounts," which qualify for the exception, and other "reductions in price," which do not, *see* SOI at 3—does not follow from the plain language of the statute. 42 U.S.C. § 1320a-7b(b)(3)(A) (referring to "a discount *or* other reduction in price").

Similarly, the arrangements here are within the plain text of the regulatory safe harbor. The safe harbor defines a discount as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction," subject to certain exceptions not relevant here. 42 C.F.R. § 1001.952(h). The safe harbor further protects rebates, defined as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase and to which the discount applies, but which is not given at the time of sale." *Id.* § 1001.952(h)(4). Because market share, volume, and formulary-based discounts, including rebates, are covered under the terms of the safe harbor, application of the safe harbor to protect such discounts turns on whether the discounts are properly disclosed by the seller to the buyer. *See id.* § 1001.952(h)(2); *see also* OIG, Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64

Fed. Reg. 63,518, 63,527-29 (Nov. 19, 1999) (recognizing that a seller need not be "the buyer's 'brother's keeper'" with respect to disclosure).[5]

As the Court correctly noted, the relators here do not allege a failure to disclose, Op. at 7—a fact that distinguishes this case from *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112 (D. Mass. 2011), upon which the Government relies. *See* SOI at 5-6. In *Lisitza*, the court held that the alleged false payments were not "properly disclosed" because, "[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not." 765 F. Supp. 2d. at 125.

Furthermore, PhRMA respectfully submits that this Court should reconsider its ruling that the regulatory discount safe harbor does not apply unless CCS "provided certain information concerning the discounts to a governmental agency pursuant to its request." Dkt. #181 at 3. The OIG's regulation on its face requires that a buyer needs to provide such information *only* "upon request" by CMS (or a State agency). 42 U.S.C. § 1001.952(h)(1)(iii). Where, as here, no governmental agency made a request for the information, CCS had no obligation—or even an appropriate mechanism—to provide it. Because the notice requirement is triggered only by a "request" from the government, the Court's August 24, 2016 decision mandating that buyers (or potentially even sellers) under a discount arrangement must notify the government in the absence of a request is both inconsistent with the safe harbor's text and in fact renders it impossible for any discount arrangement to comply with the safe harbor.[6]

[5] Some types of price reductions may also fit within other regulatory safe harbors, such as the safe harbors for price reductions offered to eligible managed care organizations. *See, e.g.*, 42 C.F.R. § 1001.952(t). Rebates to PBMs and Managed Care Organizations commonly fit in this safe harbor. Similarly, administrative fees paid to Group Purchasing Organizations fall within a safe harbor protecting those fees. 42 C.F.R. § 1001.952(j).

[6] The OIG also has recognized the benefit of protecting discounts from prosecution under the AKS, noting that "[p]ublic policy favors open and legitimate price competition in health

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II. The Government's Attempt to Regulate Through a Statement of Interest in Litigation Is Improper and Raises Serious Constitutional Concerns

Because the AKS is a criminal law, and the FCA imposes substantial penalties on violators, due process demands that the Government put would-be defendants on clear notice of conduct that would violate either the AKS or the FCA. *See United States ex rel. Purcell v. MWI Corp.,* 807 F.3d 281, 287 (D.C. Cir. 2015), *reh'g en banc denied* (2016). The Government's SOI incorrectly suggested that the Special Fraud Alert "made clear" OIG's position 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 [sic] use of such products covered by Federal health care programs." SOI at 7. As noted above, the alert actually provides that such programs raise fraud and abuse risks "unless the payment is made fully consistent with a 'safe harbor' regulation, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices." 59 Fed. Reg. 65,371, 65,372, 65,376 (Dec. 19, 1994).

The argument in the Government's SOI was thus a circular one: it insisted that the Special Fraud Alert shows that CCS's discount arrangements are actionable, but the alert simply defines payments as actionable when they are not consistent with the safe harbor. The Government's focus on a purpose to "induce" or "increase" sales was equally unhelpful. Maintaining or improving sales is typically at least one of the core purposes of any discount arrangement. It is of course true that discounts or rebates based on market share, volume, or formulary placement are likely to influence the preferred therapy for some patients. Any

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care. Thus, the AKS contains an exception for discounts offered to customers that submit claims to the federal health care programs, if the discounts are properly disclosed and accurately reported." OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,735 (May 5, 2003).

discount arrangement is likely to increase utilization of the discounted product: this is inherent in the nature of competition, which ultimately benefits consumers and the marketplace. To interpret the statutory discount exception and regulatory discount safe harbor in a manner that could exclude market share, volume, or formulary discounts would be contrary to their plain meaning and could deter various types of common discount arrangements. Congress in fact created the statutory exception and directed OIG to create a safe harbor precisely because discounts would otherwise be precluded under the plain text of the AKS—a result that Congress did not want and that would be terrible health care policy. *See, e.g.*, S. Rep. No. 95-453, at 12 (1977).

Because the Government articulated its interpretation for the first time in litigation, as opposed to notice-and-comment rulemaking under the Administrative Procedure Act, interested parties such as CCS were not on clear notice of the Government's position. To find a violation of the AKS based on a good faith interpretation of an ambiguous statute or regulation, in the absence of clear notice of the government's contrary position, would violate the defendant's due process rights. *See Johnson v. United States*, 135 S. Ct. 2551, 2557 (2015) ("[T]he indeterminacy of the wide-ranging inquiry required by the residual clause both denies fair notice to defendants and invites arbitrary enforcement by judges. Increasing a defendant's sentence under the clause denies due process of law."); *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2168 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.").

Similarly, given the severe penalties that attach under the FCA, these due process principles apply equally to that statute. *See Purcell*, 807 F.3d at 287 ("Strict enforcement of the FCA's knowledge requirement helps to ensure that innocent mistakes made in the absence of binding interpretive guidance are not converted into FCA liability, thereby avoiding the potential due process problems posed by 'penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.'"). For this reason, courts have consistently held that objectively reasonable interpretations of statutes, regulations, or contracts are not actionable under the FCA. *See United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370 (4th Cir. 2008); *United States v. Southland Management Corp.*, 326 F.3d 669, 684 (5th Cir. 2003); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999); *Crane Helicopter Servs., Inc. v. United States*, 45 Fed. Cl. 410, 434 (Fed. Cl. 1999). And to the extent the relevant language from the criminal AKS or quasi-criminal FCA is deemed ambiguous, those statutes must be construed strictly to avoid these due process concerns. *See United States v. Kozminski*, 487 U.S. 931, 952 (1988); *Crandon v. United States*, 494 U.S. 152, 158 (1990) ("[B]ecause the governing standard is set forth in a criminal statute, it is appropriate to apply the rule of lenity in resolving any ambiguity in the ambit of the statute's coverage."). CCS and others lacked clear notice of the Government's interpretation either by the plain text of the AKS or a prior OIG safe harbor regulation. This Court should not have credited the Government's position and should reaffirm its prior decision granting CCS's motion to dismiss.

III. The Proper Interpretation of the AKS Discount Exception and the OIG's Discount Safe Harbor Is Exceptionally Important and Warrants Interlocutory Review

At a minimum, this case presents an exceptionally important question concerning the proper interpretation of the AKS discount exception and the OIG's discount safe harbor. The proper interpretation of these provisions affects countless discount arrangements in the health

care sector that rely on the discount safe harbor for protection against criminal or FCA sanctions. If the Court denies reconsideration, it should grant CCS's request to certify the question for immediate appellate review under 28 U.S.C. § 1292(b) for several reasons.

First, the issue presented is a "controlling question of law," and an immediate appeal "may materially advance the ultimate termination of the litigation." Indeed, reversal of the Court's August 24, 2016 decision would result in dismissal of the claims against CCS in their entirety. 28 U.S.C. § 1292(b). Second, there is demonstrably a "substantial ground for difference of opinion." *Id.* This Court initially held that discount exception and safe harbor applied to the alleged arrangement here, before concluding that they do not apply.

Third, the proper scope of the discount exception and safe harbor is profoundly important to PhRMA's members as well as patients, payers, and others involved in health care delivery in the United States. Discounts play a critical role in reducing health care costs and encouraging competition. The Supreme Court has recognized that "cutting prices in order to increase business often is the very essence of competition" and constitutes "the very conduct the antitrust laws are designed to protect." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Manufacturers of pharmaceutical products and medical devices, for example, commonly provide discounts to purchasers of their products. These discounts ultimately reduce the cost of pharmaceutical products to patients, purchasers, and payors.

A consequence of any discount arrangement, including those in the health care space, is to encourage greater use of the discounted product. Payors and purchasers of pharmaceuticals or medical devices routinely balance cost considerations (*i.e.*, the discounts that are provided) with the clinical effectiveness of a product in determining the terms on which the product should be made available to patients. The performance-based discounts that manufacturers provide to

payors, managed care organizations, and purchasers of pharmaceuticals—whether volume-based, market share, or formulary-based—thus play a critical role in the competitive process. And, formularies by their very nature involve the recommendation of a manufacturer's product in exchange for a discount.

The Government itself relies on performance-discount mechanisms to reduce costs in its own programs. Medicaid, which provides health coverage for more than 55 million beneficiaries, uses rebates, formularies, and formulary-like drug lists to reduce costs. And, when Congress expanded Medicare in 2003 to cover outpatient prescription drugs, it did so by creating a program that relies on price competition among health plans to contain costs. Those competing plans (known as "Part D plans") establish their own drug formularies and negotiate with manufacturers to obtain price concessions. The statutory provisions governing Medicare Part D explicitly authorize this approach, using formulary rebates to reduce cost and improve care. *See* 42 U.S.C. § 1395w-104(b)(3). The Government's SOI thus rightly acknowledged that discounts encourage a competitive marketplace that ultimately benefits the Government, other payors, patients, and the entire health care system. SOI at 4 ("Congress recognized that discounts often are a good business practice which results in savings to Medicare and Medicaid program costs. . . . Accordingly, Congress created an exception to the AKS for a discount or other reduction in price.") (internal quotation marks omitted).

The narrow interpretation of the discount exception and safe harbor set forth in the Government's SOI and the Court's August 24, 2016 decision, however, put companies at risk of criminal and quasi-criminal liability under the AKS and FCA for offering beneficial discounts, particularly where the government does not request disclosure of the discount from the buyer.

For these reasons, if the Court does not grant reconsideration at this time, PhRMA respectfully requests that the Court should certify its ruling for interlocutory appeal.

CONCLUSION

For the foregoing reasons, PhRMA requests that the Court grant CCS's motion to reconsider, or to certify for interlocutory appeal, the Court's August 24, 2016 order.

Dated: September 23, 2016

Respectfully submitted,

/s/ *John A. Freedman*
John A. Freedman (BBO No. 629778)
Jeffrey L. Handwerker
(*pro hac vice* motion forthcoming)
R. Stanton Jones
(*pro hac vice* motion forthcoming)
ARNOLD & PORTER LLP
601 Massachusetts Avenue NW
Washington, DC 20001
(202) 942-5000
John.Freedman@aporter.com
Jeffrey.Handwerker@aporter.com
Stanton.Jones@aporter.com

Counsel for Amicus Curiae *Pharmaceutical Research and Manufacturers of America (PhRMA)*

CERTIFICATE OF SERVICE

I hereby certify that on September 23, 2016, I caused a true and accurate copy of the foregoing document to be filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ *John A. Freedman*
John A. Freedman