

Common Marketing Techniques Come Under Fire

Thomas W. Beimers
Gina M. Kastel
Emily Puchalski
Faegre Baker Daniels LLP
Minneapolis, MN

Introduction

Over the past several years, the U.S. Department of Justice (DOJ) has interpreted the federal Anti-Kickback Statute (AKS) in new ways that implicate standard marketing arrangements commonly used by drug and device manufacturers, and—by extension—downstream purchasers, including physician offices, pharmacies, and hospital systems. Specifically, the government has taken the position that performance-based price concessions, preferred product list (formulary) payments, and sales-related “spiffs”¹ may each represent illegal inducements. Although market share and volume-based discounts and rebates have long been considered permissible, DOJ has begun targeting arrangements it perceives as linking a discount or rebate to specific efforts to grow sales volume, as well as those arrangements in which the government believes the parties have failed to disclose all discount terms. Similarly, despite general acceptance of paying reasonable commissions on product sales, DOJ has contested the use of modest, short-term “spiff” payments to help focus attention on particular products.

It seems obvious that purchasers receiving market share or volume-based price concessions from manufacturers also will be interested in actually re-selling the products, and further that the purchasers and the manufacturers have a mutual interest in working together to market the products. The government’s position suggests, however, that these marketing activities are only permissible if they adhere to requirements that are narrow and often quite technical.

This trend is reflected in recent False Claims Act (FCA) case resolutions and settlements, and, as a result, drug and device manufacturers may now question whether these previously widely accepted practices present unacceptable risks going forward. This article summarizes recent cases addressing these issues, as well as the more recent positions taken by the government in some of these cases, and offers practical guidance on how manufacturers might avoid the pitfalls associated with these familiar arrangements going forward.

Joint Marketing Arrangements

Manufacturers frequently engage in joint marketing activities with downstream partners. For example, when a new product is introduced a manufacturer may work with its

re-sellers to introduce the product to the sales force. The manufacturer might also provide a limited-time incentive program to boost sales. Recently, such arrangements have faced increased scrutiny.

Historic Support for Discounts

The AKS exception for discounts dates back to its enactment in 1972, and the U.S. Department of Health and Human Services Office of Inspector General (OIG) followed Congress’ lead and adopted a discount safe harbor.² OIG has emphasized that discounts are “encouraged under the Federal health care programs so long as the Federal health care programs share in the discount where appropriate.”³

The safe harbor regulations define “discount” broadly to mean 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.”⁴ Discounts include rebates, which are defined to be “any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which are not given at the time of sale.”⁵ Under this definition, a rebate (including a volume-based price incentive) is a discount as long as the terms of the rebate are fixed in writing at the time of the initial sale.

DOJ’s Recent Position On Performance-Based Discounts and Rebates

Price concessions are inherently designed to induce the purchase of a good or service, and thus are fertile ground for AKS activity. Several cases exhibit the government’s theory that performance-based discounts or rebates implicate the AKS, and by extension the FCA. An early example appeared in a lawsuit against Bristol-Myers-Squibb.⁶ The complaint alleged that stocking allowances, price protection payments, and “market share payments” constituted illegal remuneration under the AKS to the manufacturer’s retail pharmacy and wholesale customers.⁷

These same theories received extended treatment in *U.S. ex rel. Banigan v. Organon USA Inc.*⁸ In pleadings filed in 2011, the parties argued over whether certain standard rebates offered to purchasers of the antidepressant Remeron were protected. The *Organon* relator alleged that rebates provided to long term care facilities as part of a “switching” program constituted impermissible remuneration under the AKS.⁹ The challenged arrangements included flat percentage discounts, market share discounts, conversion rebates, rebates tied to the placement of Remeron on formulary in a preferred position, and rebates for entering into therapeutic interchange agreements.¹⁰ The relator argued that conditioning the discounts on negotiated performance conditions (such as a certain dollar volume or percentage of sales, or inclusion on formulary or preferred lists) removed the payments from regulatory or statutory protection.¹¹ The relator further

alleged that the discount safe harbor required that all of these terms be disclosed to the government.¹²

The Pharmaceutical Research and Manufacturers of America (PhRMA) filed an amicus brief, noting that the case could have a dramatic impact on discounting and rebate practices long considered standard in the pharmaceutical industry.¹³ PhRMA pointed out that the types of market share and performance-based payments at issue in *Organon* were ordinary price concessions, very typical in the industry, that ultimately benefit payers, including federal health care programs.¹⁴ PhRMA also pointed out that formulary programs are common, and that the state Medicaid programs frequently use formularies—and require rebates—in exchange for inclusion on the state’s preferred drug list.¹⁵

In addition, both *Organon* and PhRMA argued at length that the statutory discount exception and the regulatory discount safe harbor protect price concessions, regardless of whether they are performance-based, so long as the terms of the discount or rebate are transparent.¹⁶ As PhRMA summarized, it is “axiomatic that all discounts are intended to increase the purchase of a given product.”¹⁷ Indeed, the limited guidance regarding discounts provided by OIG suggested that the government did not intend to prevent “innocuous, or even beneficial, commercial arrangements.”¹⁸

Although the government declined to intervene in *Organon*, it filed a Statement of Interest to clarify its position on the rebate issue. In its brief, DOJ stated: “Payments to pharmacies for switching patients from one drug to another, and for other efforts to increase a drug’s utilization do not qualify as protected price reductions” for purposes of the discount safe harbor or the statutory discount exception.¹⁹ The *Organon* court did not squarely address the rebate issue.²⁰ The case eventually settled,²¹ and DOJ has subsequently taken the position that the resolution supports its theory regarding performance-based price concessions.

In *U.S. ex rel. Lisitza v. Johnson & Johnson*, the court ruled that performance-based rebates paid to long term care facilities predicated on “switching” and “therapeutic interchange” programs for Johnson & Johnson’s Risperdal product did not qualify for the statutory discount exception, observing that “[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not.”²² The court did not describe the terms and conditions of the rebates that should have been explicated, nor to whom. Nor is it clear why this should have mattered, as transparency around the terms and conditions of a rebate is not an element of the discount safe harbor so long as the buyer is able to accurately calculate and report the *value* of the price concession.²³ Reading between the lines of the court’s ruling, it may be that the court was troubled by other, more mundane AKS concerns. For example, the allegations included a large payment for physician data that was of questionable utility and apparently lacked fair market valuation support.²⁴ Nonetheless, the government continues to

rely on *Lisitza* for the proposition that performance-based rebates are inherently problematic.

More recently, DOJ made a similar argument in pleadings filed in connection with *U.S. v. Novartis Pharmaceuticals Corp.*²⁵ In that case, the government alleged that Novartis paid kickbacks to specialty pharmacies to induce them to switch patients to the Novartis immunosuppressive product, Myfortic, and to recommend it over generic alternatives.²⁶ Specifically, the government alleged that pharmacies were paid to prescribe Myfortic over generic alternatives that had a lower cost and better safety profile.²⁷ Similarly, the government alleged that pharmacies were paid to prescribe the Novartis iron chelation drug, Exjade, despite the availability of a putatively safer alternative product for the same condition.²⁸

Relying on similar arguments to those raised in the *Organon* matter, Novartis argued that these arrangements were protected by the Discount Safe Harbor and related statutory exceptions.²⁹ In response, DOJ asserted that multiple “plus” factors were implicated by the Novartis arrangements with specialty pharmacies.³⁰ Specifically, DOJ alleged that the Exjade arrangements raised concerns regarding patient safety, and potentially undermined independent medical judgment, while the Myfortic arrangements implicated cost and utilization concerns.³¹ Despite what appeared to be colorable counterarguments, Novartis chose to settle the matter.³²

In the recently settled matter of *U.S. ex rel. Herman v. Coloplast Corp.*, the relators alleged that volume-based discounts and market share rebates for continence and ostomy supply products sold to durable medical equipment suppliers were not eligible for discount safe harbor or statutory exception protection because the payments were contingent on participation in promotional campaigns.³³ The relators also took the position that “spiff” incentive payments to re-seller sales representatives constituted an improper inducement to sell particular products.³⁴

In another recently settled matter, the relators alleged that Respironics, a manufacturer of sleep apnea masks, provided free call center services to medical equipment suppliers that bought its products.³⁵ Respironics asserted that it had a “good-faith belief that the [call center arrangement] offered a permissible bundled discount of Respironics’ masks and resupply services under the appropriate discount safe harbors.”³⁶ DOJ alleged that the program had the potential to compromise the supplier’s judgment regarding which products to promote.³⁷

Practical Considerations Concerning Marketing Activities

Beyond the positions taken in the above-referenced, and similar, cases, the government has otherwise provided only limited additional guidance regarding marketing activities. Much of the relevant guidance is based on long-standing, more generally applicable AKS principles. Following these general principles, the risk of an enforcement action may be

minimized if an arrangement is structured to avoid certain features that have traditionally triggered the key policy concerns that served as the basis for the AKS. According to OIG guidance, arrangements may be problematic if they:

- Interfere with or subvert independent medical decision making;³⁸
- Increase costs to federal health care programs or beneficiaries;³⁹
- Shift costs among reimbursement systems, making it difficult for government reimbursement programs to set proper price levels;⁴⁰
- Implicate patient safety or quality of care concerns;⁴¹
- Result in overutilization or inappropriate utilization of products or services;⁴² or
- Result in unfair competition.⁴³

OIG has suggested that marketing arrangements may pose less risk when they are “passive in nature”—meaning they do not involve direct contact with federal health care program beneficiaries—or when the individual or entity conducting the marketing activity is not in a “position of public trust” vis-à-vis program beneficiaries.⁴⁴

Counsel analyzing marketing arrangements should thus consider whether one of the parties to the arrangement has the ability to recommend products directly to federal health care program beneficiaries, especially where the party making the recommendation is in a position of trust (i.e., white-coat marketing).⁴⁵ Additionally, counsel should consider whether the arrangement includes other features that may draw scrutiny, such as direct billing or payment of “success” fees.⁴⁶

Based on the recent DOJ enforcement actions discussed above, parties crafting marketing arrangements should consider the following:

1. Discount and Rebate Programs

- *De-link discounts from performance obligations.* The cases discussed above underscore that DOJ views price concessions conditioned on gaining market share or providing services with suspicion, and will pursue enforcement actions if the spirit of the discount safe harbor is violated. When the parties contemplate the performance of a service, that service should not be contingent upon or compensated through a discount or rebate, as the government may take the position that an arrangement combining aspects of both a discount and a payment for services does not qualify for protection under either the discount or personal services safe harbors. Instead, the services should be the subject of a separate agreement, under which compensation is based on fair value for bona fide services actually provided.

- *Documentation is critical.* The manufacturer should clearly communicate the customer’s reporting obligations and the value of the price concession. As described in OIG Advisory Opinion 13-07, meeting the seller’s reporting obligations under the discount safe harbor is straightforward, requiring sellers only to notify the buyer of reporting obligations and provide information sufficient to permit the buyer to calculate the value of the total price concession. Advisory Opinion 13-07 also evinced a more flexible approach to bundled discounts, even where the products are reimbursed under different methodologies. Perhaps recognizing that concern about “shift[ing] costs among reimbursement systems and distort[ing] the trust cost of items” is anachronistic under contemporary reimbursement models, OIG concluded that “discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the program through lower costs.”⁴⁷
- *Disclose discount terms.* While there is no statutory or regulatory requirement that the terms and conditions of a price concession be disclosed, failure to memorialize the basis for a discount or rebate (e.g., volume or market-share commitment) may lead enforcement agencies to conclude that the discount is a disguised kickback or a payment for a service (e.g., compensation for “conversion” or “switching” activities, adherence programs, or placement on preferred-product lists).

2. Joint Marketing Activities

- *Written Agreements and Documentation.* In assessing whether a payment represents fair market value for the services performed, the government will inquire into the bona fide nature of the services, whether the services are actually performed, and whether there is a cap on the dollars allocated to the activities. If a party is able to document that services have been performed, and there is reasonable proportionality in the exchange of value, the government is less likely to be interested.
- *Fair market value.* The government is often suspicious of marketing payments, believing that they are used to disguise kickbacks for federal health care program referrals. For this reason, the parties to a joint marketing agreement should be careful to ensure that any payment is fair market value for the services actually provided. One shortcut to achieving this objective is the use of a “rate card” or other preset price list to specify the value of certain common marketing services, such as email communications or box stuffers.
- *Be aware of “plus” factors.* DOJ is far more likely to intervene in an FCA case if it can identify and articulate harm to federal health care programs or federal health care program beneficiaries. For example, in the *Johnson*

& *Johnson* and *Novartis* cases, the government alleged that the products at issue had significant risk profiles and patient safety concerns that warranted close scrutiny. In the *Organon* and *Novartis* cases, the products at issue raised cost concerns. It is instructive in this regard that the government elected not to intervene in the *Novartis* case with respect to several drug products that presumably did not lend themselves to arguments concerning overutilization, medical necessity, or risk.

3. Key Points Concerning “Spiffs”

The government may be expected to carefully scrutinize “spiff” payments in the following circumstances:

- *Where sales representatives interact directly with federal health care program beneficiaries.* The government believes that such arrangements are inherently problematic, and that a lack of transparency regarding compensation for recommending particular products raises significant “white coat marketing” issues. Even where there is an independent check, as when the item must be approved by a health care professional, DOJ believes the transparency issue raises AKS concerns.
- *Where the arrangement otherwise implicates policy considerations that typically trigger AKS enforcement decisions.* Specifically, the government will consider whether “spiff” payments may contribute to overutilization or excessive cost. For example, in connection with the *Coloplast* matter, the government has suggested publicly that patients may not have ordered ostomy or continence products but for the “spiff” payments.⁴⁸

Conclusion

Overall, manufacturers cannot rely on the long-standing acceptance of common marketing arrangements as insulation from enforcement activity. In light of recent FCA activity, manufacturers should endeavor to structure arrangements in a manner designed to provide clear definition around the types of activities at issue and the basis for price concessions or payment for services.

1 This term, also written as “SPIFF” or “SPIF,” is sometimes understood to be an acronym for Sales Promotion Incentive Fund, Special Payment Incentive for Fast Sales, or similar concepts. Generally speaking, a “spiff” refers to a de minimis, short-term sales incentive payment.

2 42 U.S.C. § 1320a-7b(b)(3)(E).

3 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999).

4 42 C.F.R. § 1001.952(h)(5).

5 42 C.F.R. § 1001.952(h)(4).

6 See Press Release, Dep’t of Justice, *Bristol-Myers-Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Sept. 28, 2007), available at www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html.

7 See *id.*

8 No. 07-cv-12153-RWZ (D. Mass. Nov. 16, 2007).

9 See, e.g., Third Am. Compl., *Organon*, 07-cv-12153-RWZ (Sept. 7, 2010) at ¶ 95; see also Mem. of Decision, *Organon*, 07-cv-12153-RWZ (June 1, 2012) at 5-6, 16.

10 Third Am. Compl., *Organon*, 07-cv-12153-RWZ at ¶¶ 94-95.

11 Relator’s Resp. to Mot. to Dismiss, *Organon*, 07-cv-12153-RWZ (Sept. 22, 2011) at 4-7.

12 Mem. of Decision, *Organon*, 07-cv-12153-RWZ at 29-30.

13 Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America, No. 07-cv-12153-RWZ (D. Mass. Oct. 27, 2011).

14 See *id.* at 1, 4-11.

15 *Id.* at 7-11.

16 See, e.g., *id.* at 13-18.

17 *Id.* at 16.

18 *Id.* (citing *U.S. v. Shaw*, 106 F. Supp. 2d 103, 119 (D. Mass. 2000) (quoting 56 Fed. Reg. 35952 (July 29, 1991)). In Advisory Opinion 98-02, OIG determined that a pricing arrangement whereby a wholesaler received discounted pricing from a pharmaceutical manufacturer in exchange for promotional support activities would not constitute prohibited remuneration under the AKS. OIG reasoned: “Implicit in any manufacturer’s discount to a wholesale purchaser is a financial incentive to the wholesale purchaser to increase its retail sales of the discounted product. That financial incentive does not change simply because the Proposed Arrangement conditions the discount on the performance of certain limited activities that directly support the resale of [the discounted products].” OIG Ad. Op. 98-02, at 8 (Apr. 8, 1998).

19 Statement of Interest on Behalf of the United States in Resp. to Defs.’ Mots. to Dismiss at 6-9, *United States ex rel. Banigan et al. v. Organon USA Inc., et al.*, No. 07-cv-12153 (D. Mass. Sept. 30, 2010).

20 883 F. Supp. 2d 277 (D. Mass. June 1, 2012).

21 Press Release, N.Y. Atty. Gen. Schneiderman, A.G. *Schneiderman Announces \$31 Million Nat’l Medicaid Settlement with Pharmaceutical Company* (Oct. 15, 2014), available at www.ag.ny.gov/press-release/ag-schneiderman-announces-31-million-national-medicare-settlement-pharmaceutical.

22 765 F. Supp. 2d 112, 125 (D. Mass. Feb. 25, 2011).

23 42 C.F.R. § 1001.952(h).

24 Mem. and Order on Def. Johnson and Johnson’s Mot. to Dismiss at 20, *Lisitz*, No. 07-cv-10288-RGS (D. Mass. Feb. 25, 2011).

25 No. 11-cv-8196-CM-JCF (S.D.N.Y. filed Nov. 14, 2011).

26 Compl.-in-Intervention of United States, No. 11-cv-8196-CM-JCF at ¶¶ 3-4 (S.D.N.Y. Apr. 23, 2013).

27 *Id.*

28 Am. Compl.-in-Intervention of United States, No. 11-cv-8196-CM-JCF at ¶¶ 1, 3, 7-10 (S.D.N.Y. Jan. 8, 2014).

29 Joint Pre-Trial Order, No. 11-cv-8196-CM-JCF at 57-62 (S.D.N.Y. June 26, 2015).

30 “Plus” factors refer to policy concerns that sometimes inform enforcement decisions. Such factors include interference with independent medical decision-making and overutilization of product or services, among others.

31 See *id.* at 10-32; see also Am. Compl.-in-Intervention of the United States, ¶¶ 60-140, 143-225, No. 11-cv-8196-CM-JCF (S.D.N.Y. Jan. 8, 2014).

32 Press Release, Dep’t of Justice, *Manhattan U.S. Atty. Announces \$370 Million Civil Fraud Settlement Against Novartis* (Nov. 20, 2015), available at www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis.

33 Second Am. Compl., ¶ 123, No. 11-CA-12131 (D. Mass. filed June 01, 2015).

34 *Id.* at ¶¶ 161-68.

35 *U.S. ex rel. Dr. John Doe v. Philips Electronics North America et al.*, No. 14-cv-2077 (D.S.C.).

36 www.dotmed.com/news/story/29891.

37 www.justice.gov/opa/pr/respironics-pay-348-million-allegedly-causing-false-claims-medicare-medicaid-and-tricare.

38 *Special Fraud Alert: Prescription Drug Marketing Schemes* (Aug. 1994), reprinted in 59 Fed. Reg. 63,376 (Dec. 19, 1994) (Marketing Schemes); *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731, 23,734 (May 5, 2003) (CPG).

39 Marketing Schemes, *supra* note 35; CPG, *supra* note 35; 56 Fed. Reg. 35,952, 35,978 (July 29, 1991).

40 CPG, *supra* note 35, at 23,734.

41 *Id.*

42 *Id.*; see also OIG Ad. Op. No. 06-16, at 6 (Oct. 3, 2006).

43 OIG Ad. Op. No. 06-16 at 5.

44 56 Fed. Reg. 35952, 35974 (July 29, 1991).

45 OIG Ad. Op. No. 11-08 at 6 (June 21, 2011).

46 See, e.g., OIG Ad. Op. No. 10-23 (Oct. 28, 2010); OIG Ad. Op. No. 99-03 (Mar. 16, 1999); and OIG Ad. Op. No. 98-10 (Aug. 31, 1998).

47 OIG Ad. Op. No. 13-07, at 5 (July 1, 2013).

48 See Press Release, Dep't of Justice, *Coloplast Corp. and Liberator Medical Agree to Pay \$3.6 Million to Resolve Kickback Allegations* (Dec. 22, 2015), available at www.justice.gov/usao-ma/pr/coloplast-corp-and-liberator-medical-agree-pay-36-million-resolve-kickback-allegations.

Fraud and Abuse Practice Group Leadership

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Jones Day
Washington, DC
(202) 879-3496
lweidenfeld@jonesday.com



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(919) 755-1800
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Minneapolis, MN
(612) 305-7699
skratz@nilanjohnson.com



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Atlanta, GA
(404) 572-2860
mpaulhus@kslaw.com



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(215) 320-6200
ker@pietragallo.com



Alex T. Krouse, Social Media Coordinator
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Fort Wayne, IN
(574) 485-2003
alexander.krouse@parkview.com



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Washington, DC
(202) 662-4610
carol.poindexter@nortonrosefulbright.com



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hoshea@jonesday.com

