

Client Alert

June 2013

Court Dismisses Challenge to Prescription Drug Copayment Coupon Program

On June 3, 2013, the US District Court for the Southern District of New York dismissed a putative class action alleging that a prescription drug copayment subsidy program was unlawful under federal racketeering and antitrust laws.¹ The ruling was a significant victory for brand-name drug companies, which increasingly are offering copayment subsidy programs—i.e. programs to provide patients with coupons to cover insurance co-pay costs—in an effort to ensure patient access to brand-name drugs and maintain market share while competing with generic alternatives.

Background

To contain prescription drug costs, health insurers offer prescription drug benefit plans that include tiered co-pay obligations designed to encourage plan members to select lower-cost drugs. These tiered co-pay obligations place brand-name drugs in a less preferred position than their generic counterparts. By requiring plan members to pay a higher co-pay for drugs in higher tiers, insurers incentivize plan members to select less expensive treatments and medication.

To neutralize co-pay incentives imposed by insurers, drug companies often offer copayment subsidy programs for their brand-name drugs. In such programs,

[i]ndividuals enroll in drug-specific programs online and provide basic information. The drug company then mails them a wallet-sized card that includes instructions to pharmacists on how to process covered prescriptions. First, the pharmacist enters information into a computerized data management system. Information about the patient, including the patient's personal co-pay obligation, is transmitted to the pharmacist from the insurance company After learning what the patient owes, the pharmacist then enters information from the co-pay card system into the secondary insurer field. The plan member pays the out-of-pocket difference between his or her co-pay and the amount subsidized by [the drug company]. Thus, the [insurer] pays the full amount of its usual payment for the branded drug in question, but the plan member pays only part (or none) of his or her ordinary co-pay. The [insurer] is never told, and has no way of knowing, that [the drug company] has paid all or nearly all of the personal co-pay obligation.²

In March 2012, two insurers, the American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan and the Sergeants Benevolent Association Health and Welfare Fund ("Plaintiffs"), filed a lawsuit against Bristol-Myers Squibb Co. and Otsuka America Pharmaceutical, Inc. ("Defendants") alleging that the copayment subsidy program that Defendants offer for Abilify® (aripiprazole)³—the Abilify Savings Card—is illegal under the Racketeer Influenced and Corrupt Organizations Act ("RICO") and the Robinson-Patman Act. McKesson Corporation administers the Abilify

¹ See *American Fed'n of State, County and Mun. Employees Dist. Council 37 Health & Sec. Plan v. Bristol-Myers Squibb Co.*, 12 Civ. 2238 (S.D.N.Y. June 3, 2013).

² *Id.*, slip op. at 4.

³ Defendants jointly market Abilify.

co-pay subsidy program for Defendants using McKesson's LoyaltyScript "coupon platform," which is widely used by brand-name drug companies.⁴ Plaintiffs alleged, for themselves and a similarly situated class of private health benefit providers, that Defendants' copayment subsidy program defrauded them in violation of RICO by "interfering with their cost-sharing provisions," thereby "causing them to pay for prescriptions of [Abilify] that they would not otherwise have paid for, and causing them to pay an inflated rate for each subsidized prescription."⁵ In addition, Plaintiffs alleged that the co-pay subsidies provided by Defendants to "individual insureds to eliminate or reduce their personal obligations under their prescription drug plans' cost-sharing plans" constituted commercial bribery in violation of the Robinson-Patman Act.⁶ The lawsuit was one of several brought in 2012 in multiple federal district courts by insurers against various drug companies in a coordinated effort to challenge co-pay subsidy programs.⁷

The Court's Decision

In a 35-page opinion, the court determined that Plaintiffs' claims should be dismissed. According to the court, Plaintiffs' RICO claim was premised on three distinct legal theories of liability, which it called the "misrepresentation theory," the "waiver theory," and the "benchmark theory."⁸ The court dismissed the RICO allegations based on the misrepresentation and waiver theories of liability with prejudice because, the court said, they "do not succeed as a matter of law," and it dismissed the RICO allegations based on the benchmark theory with "leave to replead" because those allegations lacked the "requisite specificity."⁹ The court also dismissed Plaintiffs' commercial bribery claim.¹⁰

The RICO Claims. The court held that, to allege a cognizable RICO violation, Plaintiffs needed to allege, among other things, that Defendants committed at least two predicate acts—in this case at least two acts of mail and wire fraud. To allege mail and wire fraud, the court held, Plaintiffs needed to allege that Defendants engaged in "a scheme or artifice to defraud" using "a mailing or wire transmission in furtherance of that scheme."¹¹ In relevant part, Plaintiffs alleged that Defendants engaged in a scheme to defraud Plaintiffs by:

- "[I]nterfering with their cost-sharing provisions, causing them to pay for prescriptions of [Abilify] that they would not otherwise have paid for, and causing them to pay an inflated rate for each subsidized prescription."

⁴ *American Fed'n*, slip op. at 3 ("McKesson is not a defendant in this action, but is alleged to be an unnamed conspirator."); see also *McKesson Corp., LoyaltyScript Co-Pay Discounts* (last visited June 6, 2013) ("LoyaltyScript, McKesson's market-leading coupon platform allows brands to address cost, one of the main reasons cited for non-adherence and prescription abandonment."), available at http://mprsannounce.mckesson.com/MPRS/microsite/loyaltyscript_co-pay_discounts.htm.

⁵ *American Fed'n*, slip op. at 8-9.

⁶ *Id.*, slip op. at 23-24.

⁷ See *New England Carpenters Health & Welfare Fund v. Abbott Labs.*, No. 12-cv-01662 (N.D. Ill. filed Mar. 7, 2012); *New England Carpenters Health & Welfare Fund v. AstraZeneca*, No. 12-cv-01192 (E.D. Pa. filed Mar. 7, 2012); *New England Carpenters Health & Welfare Fund v. GlaxoSmithKline*, No. 12-cv-01191 (E.D. Pa. filed Mar. 7, 2012); *Plumbers & Pipefitters Local 572 Health & Welfare Fund v. Novartis Pharmaceuticals Corp.*, No. 12-cv-01403 (D.N.J. filed Mar. 7, 2012); *Plumbers and Pipefitters Local 572 Health & Welfare Fund v. Merck & Co.*, No. 12-cv-01379 (D.N.J. filed Mar. 7, 2012); *AFSCME District Council 37 Health & Security Plan and Sergeants Benevolent Association Health & Welfare Fund v. Amgen Inc. and Pfizer Inc.*, No. 12-cv-2237 (S.D.N.Y. filed Mar. 27, 2012); *Laborers' Int. Union of N. Am. Local 17 Health & Benefit Fund v. Pfizer, Inc.*, No. 12-cv-02665 (E.D.N.Y. filed May 12, 2012); *Allied Services Division Welfare Fund v. Pfizer, Inc.*, No. 3:12-cv-00764 (S.D. Ill. filed July 5, 2012); *Allied Services Division Welfare Fund v. Merck & Co.*, No. 3:12-cv-00766 (S.D. Ill. filed July 6, 2012); *Allied Services Division Welfare Fund v. Novartis Pharmaceuticals Corp.*, No. 3:12-cv-00775 (S.D. Ill. filed July 6, 2012); *United Food and Commercial Workers International Union, Local 1776 Health & Welfare Fund v. Novartis Pharmaceuticals Corp.*, No. 12-cv-04694 (D.N.J. filed July 26, 2012); *United Food and Commercial Workers International Union, Local 464A Health & Welfare Fund v. Novartis Pharmaceuticals Corp.*, No. 12-cv-03627 (D.N.J. filed June 15, 2012); *United Food and Commercial Workers International Union, Local 464A Health & Welfare Fund v. Merck & Co.*, No. 12-cv-03652 (D.N.J. filed June 15, 2012).

⁸ See *American Fed'n*, slip op. at 10.

⁹ *Id.*

¹⁰ See *id.*, slip op. at 34.

¹¹ *Id.*, slip op. at 7 (quotation omitted).

- “[C]ausing misrepresentations to be made via the wires at the time of the point of sale transaction—that is, when the member presents the co-pay card at the pharmacy—when, as instructed by the defendants, the pharmacists electronically charges the health benefit provider the full benchmark price without accounting for the existence of co-pay subsidies (as instructed by defendants).”
- “[R]eporting benchmark prices to reporting agencies while failing to account for the routine waiver of co-pays.”¹²

According to the court, these allegations show that Defendants’ “co-pay subsidy program is not a fraud on anyone because it involves no element of deception. . . . [T]he allegations . . . show only that Plaintiffs believe that the co-pay subsidy program is counter to their business objectives.”¹³

With regard to Plaintiffs’ **misrepresentation theory**, the court determined that Plaintiffs did not allege that they had “received any records containing misrepresentations of the sort that could ground a claim for fraud.” Specifically, Plaintiffs did not allege that they had “been provided with any records from either Defendants or pharmacies falsely stating that an insured paid the co-pay unaided by a co-pay subsidy coupon.” Similarly, Plaintiffs did not allege any

active deception in the pharmacists’ point-of-sale statements to [Plaintiffs] that insureds have satisfied their co-pay obligation—at least, no more so than would be the case if an insured got the money to cover the cost from his rich uncle or a stranger on the street, as opposed to his own pockets.

Moreover, Plaintiffs did not allege any duty (contractual or otherwise) “that would require either Defendants or pharmacies to disclose to [Plaintiffs] when a plan member uses a co-pay subsidy card provided by Defendants.”¹⁴

With regard to Plaintiffs’ **waiver theory**, the court acknowledged that health insurers may create contracts that relieve them of the duty to pay physicians who routinely waive co-pays, but concluded that

there is no waiver of the co-pay by Defendants when insureds fill prescriptions for Abilify. . . . Plaintiffs identify no basis for treating as fraudulent *the provision* of a subsidy that allows pharmacies to ‘waive’ a fee. Of course, this is all speculative, since there is not *actually* any waiver. Pharmacies collect the full amount of the co-pay obligation every time, either from the patient or [Plaintiffs]. Failure to do so would force the pharmacy to bear that cost.

In sum, the court held, “there is no deception, misrepresentation, or omission involved” when drug companies subsidize co-pays.¹⁵

Finally, the court determined that Plaintiffs’ **benchmark theory**—i.e. that Defendants failed to account for co-pays when price reporting, thereby defrauding Plaintiffs—“pivots on vague and general pleadings” that make it impossible for the court to “determine whether the Complaint states a claim upon which relief could be granted.”¹⁶ Accordingly, the court granted Plaintiffs leave to replead this claim with more particularity.

The Commercial Bribery Claim. As for Plaintiffs’ commercial bribery claim, the court held that the

¹² *Id.*, slip op. at 9.

¹³ *Id.*, slip op. at 9-10.

¹⁴ *Id.*, slip op. at 11-12.

¹⁵ *Id.*, slip op. at 18-19 (emphases in original).

¹⁶ *Id.*, slip op. at 23.

“essence of commercial bribery is the corruption of the duty that an agent owes his principal.”¹⁷ Thus, to allege a viable claim, Plaintiffs needed to allege that “patients owe [a fiduciary duty] to their insurance companies in selecting medications or obtaining money to cover their co-pay obligations.”¹⁸ Plaintiffs, however, failed to do so. According to the court, Plaintiffs

do not quote or reference any provision of [their agreements with insureds] that creates any duty on the part of insureds to act ‘for or in behalf of’ the insurer in obtaining, filling, and financing prescriptions. Nor do they point to any provision that indicates that insureds act as agents or as intermediaries of insurers in choosing which medication to be prescribed or which prescriptions to fill. Even to the extent that patients play a role in selecting which medications their physician will prescribe, the Complaint lacks plausible allegations demonstrating that patients act ‘for or in behalf of the insurer’—rather than ‘for or in behalf of’ their personal welfare—in making such choices.

Accordingly, the court dismissed Plaintiffs’ commercial bribery claim.

Conclusion

The court’s dismissal of Plaintiffs’ RICO and commercial bribery claims comes just over a month after the US District Court for the District of New Jersey dismissed three similar suits for failure to sufficiently plead causation.¹⁹ One of those suits alleged not only RICO and commercial bribery claims, but also a tortious interference with contract claim (which alleged that the defendant drug company’s copayment subsidy program unlawfully interfered with the plaintiff insurer’s contracts with its health plan members). Although these recent dismissals suggest that the plaintiffs in co-pay subsidy program lawsuits face significant hurdles, several similar cases are still pending in various federal courts. It remains to be seen whether plaintiffs in those cases will meet similar fates.

How We Can Help

Hunton & Williams’ food and drug practice has extensive experience advising clients on prescription drug rebate programs, discounts, government pricing, and related matters. If you need assistance in evaluating your options, please contact us.

Contacts

D. Kyle Sampson
ksampson@hunton.com

Sharon M. Bradley
sbradley@hunton.com

© 2013 Hunton & Williams LLP. Attorney advertising materials. These materials have been prepared for informational purposes only and are not legal advice. This information is not intended to create an attorney-client or similar relationship. Please do not send us confidential information. Past successes cannot be an assurance of future success. Whether you need legal services and which lawyer you select are important decisions that should not be based solely upon these materials.

¹⁷ *Id.*, slip op. at 26.

¹⁸ *Id.*, slip op. at 29. The court noted that it “would be hard to comprehend the scope of any such fiduciary duty—e.g., must patients pressure physicians to choose generics, or act faithfully to the insurer in deciding where and how to obtain the money necessary for co-pay obligations?” *Id.*

¹⁹ See *Plumbers & Pipefitters Local 572 Health & Welfare Fund v. Merck & Co.*, No. 3:12-cv-01379-MAS-LHG (D.N.J. Apr. 29, 2013); *United Food & Comm’l Workers Int’l Union, Local 464A Health & Welfare Fund v. Merck & Co.*, No. 12-cv-03652-MAS-LHG (D.N.J. Apr. 29, 2013); *Allied Servs. Div. Welfare Fund v. Merck & Co.*, No. 12-cv-7027-MAS-LHG (D.N.J. Apr. 20, 2013). In all three cases, the court granted the plaintiffs leave to amend their complaints. See, e.g., *Plumbers & Pipefitters*, slip op. at 14.