

## RICO Suits Challenge Off-Label Drug Marketing

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Physicians often prescribe drugs for uses not approved by the U.S. Food and Drug Administration. Although this so-called “off-label” use is generally lawful and may be medically sound, the cost of expanding uses may pose challenges for insurers, who must carefully manage coverage decisions. Moreover, pharmaceutical companies that promote drugs for off-label uses may be subject to criminal and civil liability. Because drug reimbursement often involves government payors, such as Medicare and Medicaid, both the government and private relators have for years pursued False Claims Act cases alleging that off-label promotion resulted in inappropriate reimbursements. In 2014, the government recovered more than \$235 million from pharmaceutical companies in FCA settlements relating to off-label promotion, but similar settlements in recent years have ranged into the billions.



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Although FCA cases generally are limited to conduct involving government payors, private payors have recently sought to challenge the same conduct using a different legal vehicle: the federal Racketeering Influenced and Corrupt Organizations Act.[1] In the well-publicized *In re Neurontin Marketing and Sales Practices Litigation* suits, for example, multiple payors brought RICO claims against a pharmaceutical company and its subsidiary in the wake of their \$430 million resolution of FCA and federal Food, Drug and Cosmetic Act (FDCA) investigations. One of the payors secured a \$140 million judgment after a jury trial, and several others settled with the defendant for \$325 million.

This article summarizes recent case law applying RICO where a private third-party payor alleges that a pharmaceutical company improperly promoted — and therefore impermissibly increased the number of prescriptions for — its products, thereby causing the payors economic injury.

### Brief Summary of the FCA and RICO

The federal government views the FCA as its primary weapon in protecting the public fisc from fraud against government agencies and programs. Under the FCA, a person who submits a false claim to the government (or causes another to do so) — or makes a false record or statement material to a claim — may be liable for civil penalties (ranging from \$5,500 to \$11,000 per false claim), treble damages and attorneys’ fees.[2]

Whereas the FCA seeks to redress fraud on the government, RICO takes aim at organizations that engage in a consistent pattern of conduct prohibited by specified state or federal laws (so-called RICO predicates).[3] RICO is a complex statute, however, with numerous challenges of pleading and proof. Isolated predicate acts cannot support a RICO conviction or civil judgment. Rather, there must be several continuous and related predicate acts.[4] A RICO suit must identify an “enterprise” distinct from the defendant — a group that has a purpose and relationships among its associates, so long as it has existed for a sufficient period of time to pursue its purpose.[5] And a RICO plaintiff must show that the RICO violation was both the but-for and proximate cause of an injury to the plaintiff’s “business or property.” [6] The plaintiff that can satisfy these complex requirements stands to be richly rewarded, as RICO provides for treble damages, along with mandatory costs and attorneys’ fees.[7]

### **Key Legal Issues in RICO Suits Mirroring FCA Suits Against Pharmaceutical Companies**

In many respects, private payor RICO suits mirror the government’s (and relators’) FCA suits. But the key legal issues raised in a RICO suit often differ significantly from those in FCA litigation, as several recent cases illustrate.

In re Neurontin[8] has garnered the most publicity among these suits — and it is representative of the issues that arise in these cases. In May 2004, Pfizer Inc., and its subsidiary Warner-Lambert Co., resolved government allegations that one of Warner-Lambert’s operating divisions violated the FDCA and FCA by promoting Neurontin for off-label uses. The allegations, first leveled in a qui tam complaint filed by a former employee of the operating division, resulted in criminal and civil settlements totaling approximately \$430 million.[9] As part of the criminal plea agreement, Warner-Lambert admitted to promoting Neurontin for several off-label uses.[10]

Less than a year after the U.S. Department of Justice disclosed the settlement, multiple private third-party payors filed a coordinated RICO suit against Pfizer and Warner-Lambert. The payors claimed that the defendants presented false and misleading information about the safety and effectiveness of Neurontin for off-label uses and that the marketing targeted both physicians and payors in an effort to “influence both formulary decisions and prescribing decisions.”[11] The payors alleged that the off-label promotion caused physicians to prescribe Neurontin at a higher rate for off-label uses than they would have otherwise, causing the payors injury (because other, allegedly more appropriate medications would have been less expensive for the payors).[12]

The First Circuit issued several decisions supporting the payors’ RICO theories. In affirming a \$140 million jury verdict for one payor (Kaiser Foundation Health Plan Inc.) against Pfizer, the First Circuit held that Kaiser’s theory of proximate causation was not too attenuated: “the effect of that wrongful conduct was clear in foresight” because the defendants intended to increase Neurontin prescriptions through the marketing activity.[13] The court also held that the evidence sufficed to show but-for causation, noting that Kaiser introduced evidence that its employees relied on Pfizer’s marketing and an expert report asserting — based on statistical analyses — that the off-label promotion caused physicians to write more Neurontin prescriptions than they would have absent such marketing.[14]

Further, in two separate opinions, the First Circuit reversed grants of summary judgment to Pfizer on the claims of a second third-party payor and a putative class of self-insured employers. The court concluded that the payors’ aggregate statistical evidence that the promotion was the but-for cause of additional off-label Neurontin prescriptions — and circumstantial evidence bolstering that conclusion — sufficed to raise triable issues of fact.[15] On remand, Pfizer settled the outstanding actions for \$325 million.[16]

The court decisions in the *In re Neurontin* litigation present continuing risk for pharmaceutical companies under RICO.[17] But other legal obstacles remain. For example, the courts have dismissed several RICO suits because the plaintiff payors failed to allege economic injury arising from the defendant pharmaceutical company's allegedly illegal marketing. In *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals*, for example, the Eleventh Circuit affirmed a district court's dismissal of a RICO claim because the plaintiff insurers failed to adequately allege that the defendant pharmaceutical company's purported misrepresentations (in allegedly promoting the drug Seroquel off-label) caused the plaintiffs economic injury.[18] Specifically, the court found that the plaintiff insurers agreed to cover Seroquel "even if the prescription was medically unnecessary or inappropriate" because Seroquel appeared on the insurers' formularies, without a preauthorization review requirement for off-label uses.[19] Reasoning that the plaintiffs must therefore have anticipated off-label use of Seroquel and factored the costs of medically unnecessary or inappropriate uses into their premiums, the Eleventh Circuit concluded that the plaintiff insurers had not plausibly pleaded any economic loss.[20]

Further, a payor pursuing a RICO claim may be unable to adequately demonstrate, for Article III standing purposes, an injury fairly traceable to the defendant pharmaceutical company's conduct. In *In re Schering Plough Corp. Consumer Class Action*, the Third Circuit affirmed dismissal of a RICO claim premised on alleged off-label promotion and Anti-Kickback Statute (AKS) violations.[21] Like the district court, the Third Circuit concluded that the payors lacked Article III standing because they did not adequately allege a fairly traceable connection between their purported injuries (payments for a drug that was allegedly ineffective and unsafe) and the defendant's promotional efforts, which allegedly focused on a different drug.[22]

### **Noteworthy Differences Between RICO and FCA Suits**

The RICO cases summarized above — and the underlying statutory schemes — highlight several potentially important differences between RICO and FCA suits:

- ***Plaintiffs***. A plaintiff may sue under RICO only when injured in its business or property by racketeering activity. But the FCA's qui tam provisions allow anyone to sue directly on the government's behalf and then claim a portion of any recovery.
- ***Defendants/Enterprise***. RICO requires pleading and proving an enterprise distinct from the defendant. The FCA has no such requirement.
- ***Public Disclosure***. As the cases summarized above demonstrate, nothing in RICO precludes follow-on litigation after an FCA settlement. The FCA, by contrast, bars relators from pursuing claims based on allegations that are substantially similar to information disclosed in various enumerated public sources (unless the relator qualifies as an "original source" of the information).[23] Further, the FCA's first-to-file bar precludes relators from bringing a suit based on the facts underlying a pending action.[24]

- **Causation.** RICO requires a civil plaintiff to prove both but-for and proximate causation, but the causation standards under the FCA may be less clear. For example, the AKS, as amended in 2010, provides that claims “resulting from” AKS violations are false or fraudulent for purposes of the FCA.[25] Yet courts applying this language thus far in the FCA context have resisted the argument that this language includes a but-for causation requirement.[26] But the federal district courts have only recently begun to interpret that provision, and no appellate court has weighed in on the issue.

## Conclusion

As both the FCA settlements and the RICO cases discussed above show, litigation in these matters may result in massive liabilities. In light of this evolving area of exposure, pharmaceutical companies would be wise to consider the possibility of a follow-on RICO suit when litigating and settling FCA claims and they can be sure that private payors will be keeping an eye on significant FCA settlements involving pharmaceutical companies.

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[1] See, e.g., *Sidney Hillman Health Center of Rochester v. Abbott Labs Inc.*, 782 F.3d 922 (7th Cir. 2015) (reversing decision that dismissed, on statute of limitations grounds, a health benefit plan’s RICO suit against pharmaceutical company that allegedly promoted products off-label and violated the Anti-Kickback Statute after the company’s \$1.6 billion resolution of FDCA and FCA investigations). Because the AKS and the FDCA’s criminal provisions are not RICO predicates, these suits tend to invoke the federal mail and wire fraud statutes (while nevertheless leveling off-label promotion or AKS allegations). See, e.g., *Ironworkers Local Union 68 v. AstraZeneca Pharmacies LP*, 634 F.3d 1352 (11th Cir. 2011).

[2] 31 U.S.C. §§ 3729(a), 3730.

[3] 18 U.S.C. § 1962(c), (d).

[4] 18 U.S.C. § 1961(5); *H.J. Inc. v. Nw. Bell*, 492 U.S. 229 (1989).

[5] *Boyle v. United States*, 556 U.S. 938, 944–46 (2009).

[6] *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992).

[7] 18 U.S.C. § 1964(c); see also *Sedima SPRL v. Imrex Co.*, 473 U.S. 479, 496 (1985).

[8] *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013); see also *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 51 (1st Cir. 2013) (reversing grant of summary judgment for Pfizer against Aetna in RICO suit); *In re Neurontin Marketing and Sales Practices*

Litigation, 712 F.3d 60 (1st Cir. 2013) (reversing grant of summary judgment for Pfizer against putative class of self-insured employers).

[9] 712 F.3d at 31.

[10] *Id.*

[11] *Id.* at 28.

[12] *Id.* at 28–33.

[13] *Id.* at 39.

[14] *Id.* at 40.

[15] 712 F.3d at 53; see also 712 F.3d at 62.

[16] *In re Neurontin Marketing and Sales Practices Litigation*, 58 F. Supp. 3d 167, 170 (D. Mass. 2014).

[17] See, e.g., *Se. Laborers Health and Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 410 (11th Cir. 2011) (affirming dismissal of payor's RICO suit for failure to adequately plead proximate causation).

[18] 634 F.3d at 1368–69.

[19] *Id.* at 1364–66.

[20] *Id.* In *In re Neurontin*, the First Circuit distinguished *Ironworkers Local Union 68* on the ground that the Eleventh Circuit did not decide the case on causation grounds. 712 F.3d at 46–47.

[21] 678 F.3d 235, 239 (3d Cir. 2012).

[22] *Id.* at 248. In *In re Neurontin*, the First Circuit distinguished *In re Schering Plough Corp.* on the basis that the payor there did not offer aggregate evidence linking the alleged harm to promotion of the specific drug at issue. 712 F.3d at 47.

[23] See 31 U.S.C. § 3730(e)(4).

[24] See 31 U.S.C. § 3730(b)(5); see also *Kellogg Brown & Root Services Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1979 (2015).

[25] 42 U.S.C. § 1320(a)-7b(g) (2013).

[26] See *United States ex rel. Kester v. Novartis Pharmaceutical Corp.*, 41 F. Supp. 3d 323, 331–32 (S.D.N.Y. 2014).

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