

# Ninth Circuit Decision Increases Risk of RICO Economic Loss Claims Against Pharmaceutical Manufacturers and Highlights Evolving Circuit Split

March 6, 2020

On February 26, 2020, a petition for writ of certiorari was filed in the U.S. Supreme Court seeking review of a recent decision by the U.S. Court of Appeals for the Ninth Circuit that reversed a district court's dismissal of civil claims filed against pharmaceutical manufacturers under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961 et seq. ("RICO"). In *Painters vs. Takeda*, the Ninth Circuit held that plaintiffs, consisting of individual consumers and a third-party payor ("TPP"), had satisfied RICO's proximate causation requirement at the pleading stage merely by alleging that they would not have paid for a drug had they known of a previously undisclosed safety risk.<sup>1</sup> The "central dispute," as recognized by the Court, was whether the independent decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of causation between a drug manufacturer's alleged statements or omissions and plaintiffs' purchases. The Court permitted the claims to proceed on the basis that plaintiffs were immediate victims of the manufacturers' alleged scheme to conceal safety risks.

The *Painters* decision is noteworthy given its conclusion that generalized allegations of proximate causation are sufficient to state a civil RICO claim. The decision is the latest in a series of appellate court rulings addressing the causation standard applicable to RICO economic loss claims premised on allegedly fraudulent marketing practices by drug manufacturers. This ruling demonstrates the growing risks posed by such claims and crystallizes an evolving circuit split that would benefit from Supreme Court review.

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## BACKGROUND

In *Painters*, the defendant manufacturers had developed and marketed the drug Actos, which was approved by the U.S. Food and Drug Administration (the "FDA") in 1999 for the treatment of type 2 diabetes. In 2011, the FDA warned that long-term use of Actos

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<sup>1</sup> *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243 (9th Cir. 2019) ("*Painters*").

may be linked to a heightened risk of bladder cancer. The manufacturers subsequently revised Actos's label to warn of a risk of bladder cancer.

In July 2014, plaintiffs filed a civil RICO complaint alleging that the defendants failed to revise Actos's label or take other steps to notify the public of the alleged risk prior to 2011, despite studies known by the manufacturers suggesting an increased risk of bladder cancer. Plaintiffs alleged that the defendants conspired to commit mail and wire fraud by misleading physicians and the public about the risks of long-term use of Actos. Plaintiffs sought solely monetary damages for purchases of the drug and purported to represent a class of consumers and TPPs who had paid for Actos since 1999.

To establish standing under the civil RICO statute, a plaintiff must demonstrate that she suffered a concrete injury to business or property "by reason of" a RICO violation. 18 U.S.C. § 1964(c). The proximate cause requirement serves to bar suits premised on alleged harm that is too remote from a defendant's allegedly unlawful conduct. The *Painters* plaintiffs did not allege that any specific misrepresentation or omission was made to them or their prescribing physicians. Instead, plaintiffs alleged generally that they would not have paid for Actos but for the omitted safety information, theorizing that physicians would not have prescribed the drug, nor would consumers or TPPs have paid for the drug, had they known of its risks. Plaintiffs supported their theory of causation with a survey showing that 75% of surveyed physicians' interest in prescribing a different oral anti-diabetic drug declined greatly once they learned that it carried a risk of causing bladder cancer. Plaintiffs also alleged that sales of Actos decreased approximately 80% once the FDA issued its warning.

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## PRIOR CIRCUIT COURT RULINGS

Several circuit courts have addressed similar RICO claims filed against drug manufacturers based on generalized theories of proximate causation, with diverging results.

In *Sidney Hillman v. Abbott Labs.*, the TPP plaintiffs sought to recover reimbursement costs for the drug Depakote.<sup>2</sup> The TPPs alleged that the defendant manufacturer engaged in an off-label marketing campaign involving misrepresentations to physicians about the drug's safety and efficacy. There was no allegation of misrepresentations made to the TPPs. The Seventh Circuit affirmed the complaint's dismissal on the ground that the allegations were "several levels removed in the causal sequence" from the TPPs' reimbursements. Specifically, physicians, who were the recipients of the alleged

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<sup>2</sup> *Sidney Hillman Health Ctr. v. Abbott Labs.*, 873 F.3d 574 (7th Cir. 2017).

misrepresentations, “may not have changed their prescribing practices at all, or they might have changed them but done so in response to information that [the defendant] did not influence.”<sup>3</sup>

In *UFCW Local 1776 v. Eli Lilly & Co.*, the Second Circuit rejected similar claims by TPP plaintiffs alleging that the defendant manufacturer made misrepresentations to physicians about the safety and efficacy of Zyprexa.<sup>4</sup> The plaintiffs argued that they paid for prescriptions that would not have been prescribed but for the alleged misrepresentations, relying on expert testimony showing a decline in off-label prescriptions following a label change and “Dear Doctor” letter. The Second Circuit, reversing class certification, held that “this theory of causation is interrupted by the independent actions of prescribing physicians” who may or may not have been influenced by the alleged marketing campaign.<sup>5</sup> In *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, the Second Circuit again rejected TPP plaintiffs’ attempt to rely on generalized proof of proximate causation.<sup>6</sup> The plaintiffs alleged that they paid for prescriptions of the antibiotic Ketek that would not have been written if the defendant manufacturers had not concealed safety risks. Affirming the denial of class certification, the Second Circuit reiterated that generalized proof, such as a sales decline following disclosure of allegedly hidden risks, is insufficient to prove that each class member was injured by an alleged misrepresentation given the individualized nature of physicians’ prescribing decisions.

On the other hand, two courts of appeal had endorsed RICO claims premised on generalized proof of proximate causation prior to the Ninth Circuit’s decision in *Painters*. In *In re Neurontin Marketing and Sales Practices Litigation*, the First Circuit held that a TPP satisfied RICO’s proximate cause requirement by producing aggregate statistical evidence suggesting that alleged fraudulent marketing of the drug Neurontin to physicians increased off-label prescriptions, together with evidence of an increase in prescriptions following commencement of the alleged marketing scheme.<sup>7</sup> Despite a lack of direct evidence linking a misrepresentation to an actual prescribing decision, the First Circuit concluded that the causal chain was “anything but attenuated” given that the manufacturer “relied on the expectation that physicians would base their prescribing decisions in part” on the alleged marketing scheme.<sup>8</sup> Thus, a reasonable jury could

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<sup>3</sup> *Id.* at 577.

<sup>4</sup> *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010) (rejecting RICO claims seeking monetary damages incurred in connection with purchases of Zyprexa allegedly caused by off-label marketing campaign).

<sup>5</sup> *Id.* at 135.

<sup>6</sup> *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015) (rejecting RICO claims seeking monetary damages in connection with purchases of Ketek allegedly caused by failure to disclose safety risks).

<sup>7</sup> *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013).

<sup>8</sup> *Id.* at 39.

conclude that the marketing campaign induced physicians to write additional prescriptions paid for by the plaintiff.<sup>9</sup>

Finally, in *In re Avandia*, the Third Circuit affirmed a district court's refusal to dismiss RICO claims brought by TPPs alleging that purchases of the diabetes drug Avandia were fraudulently induced by the defendant manufacturer's failure to disclose safety risks to physicians and the public.<sup>10</sup> The plaintiffs sufficiently pleaded proximate causation at the motion-to-dismiss stage by alleging that "drug manufacturers are well aware that TPPs cover the cost of their drugs" and by describing the alleged RICO scheme as consisting of "deliberately misrepresenting the safety of Avandia so that" TPPs would pay for the drug.<sup>11</sup> The Third Circuit concluded that TPPs were a direct and foreseeable victim of the alleged fraud.

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## THE NINTH CIRCUIT'S RULING

On February 1, 2018, U.S. District Judge Stephen Wilson, Central District of California, relying on the reasoning in *Sidney Hillman v. Abbott Labs.*, dismissed the RICO claims in *Painters* on the ground that plaintiffs failed to sufficiently allege proximate causation.<sup>12</sup>

On December 3, 2019, the Ninth Circuit reversed. The Court held that plaintiffs had adequately pleaded proximate causation by alleging that they would not have paid for Actos but for the allegedly omitted safety information. The Ninth Circuit recognized that the issue before it has "caused an apparent circuit split among four of our sister circuits." The Ninth Circuit sided with the First and Third Circuits, explaining that although prescribing physicians function as intermediaries between an alleged fraudulent marketing scheme and a plaintiff's purchases, it was entirely foreseeable that "physicians who prescribed Actos would play a causative role in Defendants' alleged fraudulent scheme to increase Actos's revenues." The Court opined that the approach of the Second and Seventh Circuits would effectively insulate manufacturers from liability arising from fraudulent marketing schemes or failure to disclose known safety risks.<sup>13</sup>

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<sup>9</sup> It should be noted that this decision followed a jury trial resulting in a verdict for the plaintiff.

<sup>10</sup> *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015).

<sup>11</sup> *Id.* at 645.

<sup>12</sup> Order, *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, No. 2:17-cv-07223-SVW-AS (C.D. Cal. Feb. 1, 2018) (DE 140).

<sup>13</sup> *Painters*, 943 F.3d at 1257.

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## IMPLICATIONS

The *Painters* decision has potentially significant implications for pharmaceutical manufacturers facing RICO claims in the Ninth Circuit. Damages associated with class-wide RICO claims premised on alleged fraudulent marketing of a prescription drug can be staggeringly high given the volume of prescriptions typically at issue and RICO's treble damages provision. The *Painters* decision suggests that plaintiffs in the Ninth Circuit can overcome a motion to dismiss based on broad allegations of foreseeability and without alleging a causal connection between purchasing decisions and the alleged misrepresentations or omissions. Although the Court was careful to note that it expressed no opinion on plaintiffs' ultimate chances of success in the litigation, the ability to overcome a motion to dismiss will expose defendants to expensive discovery and additional motion practice, at a minimum.

More generally, the decisions of the First, Third, and Ninth Circuits reflect a worrisome trend in RICO cases alleging fraudulent marketing practices by drug manufacturers. The rulings take a liberal view of RICO's proximate cause requirement that disregards the role of physicians' independent prescribing decisions in the causal chain. By permitting plaintiffs to rely on statistical and circumstantial evidence, these courts expose drug manufacturers to potentially enormous liability for purchases of prescriptions having no connection to the alleged fraudulent marketing.

Moreover, typical causation-based defenses will be more difficult to establish at the class certification stage in these circuits. In combination with recent precedent suggesting that RICO's injury requirement can also be satisfied through use of generalized evidence,<sup>14</sup> these cases raise the specter of "fraud-on-the-market" style claims brought on a class-wide basis by plaintiffs who rely solely on generalized evidence that a drug was improperly marketed or was ineffective or unsafe. For example, an argument that predominance is lacking because the plaintiff would need to prove that each class member and/or their prescribing physicians were exposed to or influenced by a misrepresentation, or that a drug was ineffective or unsafe for them personally, may be insufficient to defeat class certification.

On February 26, 2020, the *Painters* defendants filed a petition for writ of certiorari asking the U.S. Supreme Court to resolve the question of "[w]hether the chain of causation between a manufacturer's allegedly false or misleading statements or omissions and end payments for prescription drugs is too attenuated to satisfy RICO's

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<sup>14</sup> See, e.g., *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 915 F.3d 1 (1st Cir. 2019) (concluding plaintiffs raised triable issue as to RICO injury by presenting negative clinical studies of FDA-approved antidepressants, despite producing no individualized evidence of inefficacy).

proximate cause requirement[.]”<sup>15</sup> Although several certiorari petitions on this issue have been denied,<sup>16</sup> the Ninth Circuit’s lengthy discussion of a circuit split may tip the scale in favor of review. Such review would help clarify the proper interpretation of the RICO statute’s proximate cause requirement in cases implicating eye-popping exposure and ensure uniform application of the law. Pharmaceutical manufacturers should monitor developments in this evolving area and adjust their legal strategies accordingly.

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Please do not hesitate to contact us with any questions.

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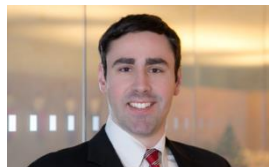
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<sup>15</sup> Petition for Writ of Certiorari, *Takeda Pharmaceutical Co. v. Painters and Allied Trades District Council 82 Health Care Fund*, No. 19-1069 (U.S. Feb. 28, 2020).

<sup>16</sup> Petition for Writ of Certiorari, *In re: Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, No. 15-1078 (U.S. Feb. 23, 2016); Petition for Writ of Certiorari, *Sergeants Benevolent Ass’n Health & Welfare Fund, v. Sanofi-Aventis U.S. LLP*, No. 15-1525 (U.S. June 17, 2016); Petition for Writ of Certiorari, *Pfizer Inc., v. Kaiser Found. Health Plan, Inc.*, No. 13-289, (U.S. Aug. 30, 2013); Petition for Writ of Certiorari, *Sergeants Benevolent Ass’n Health & Welfare Fund, v. Eli Lilly & Co.*, No. 10-1173 (U.S. Mar. 25, 2011).