

New Healthcare Lien Recovery Theories by Third-Party Payors: Strategies and Tactics for the Defense

By **Matthew Keenan** and
Christopher J. Kaufman

MOST ATTORNEYS remember the “good ole days” when health care liens on recoveries were simple and generally speaking, the “plaintiff attorneys’ problem” since no funds were ever paid until plaintiff’s counsel had settled the lien. And while this traditional model of third-party payor (“TPP”) recovery remains viable, in these days of mass tort, suddenly, health insurance carriers have identified a far more threatening, expensive and dangerous means of recovering all of their losses in one fell-swoop: suing the alleged tortfeasors *directly*. With this strategic shift, defense counsel must stay attuned to the ever-changing complexity of TPP litigation. This article examines various approaches health insurers are employing to recover losses in the aggregate and also discusses strategies defense counsel should consider using to defeat such claims.

I. The Role of Third Party Payors in the American Health Care System

Today’s health care system is one in which employers provide, either in the form of their own funds or through insurance, for their employees’ medical needs. To operate, insurers charge their enrollees an upfront fee, *i.e.* a “premium”, in exchange for insurance coverage.¹ The

¹ *Ironworkers Local Union 68 v. Astrazeneca Pharms., LP*, 634 F.3d 1352, 1364 (11th Cir.



Matt Keenan is a partner in Shook, Hardy & Bacon's pharmaceutical and medical device practice group where he has practiced for 26 years.

Recently he successfully defended a major medical device manufacturer against TPP claims in state and federal court.

Christopher J. Kaufman is an associate in the firm. He is a member of the firm's pharmaceutical and medical device practice group and represents manufacturers in individual and complex product liability litigation.



value of the premium is continually adjusted by the insurer over time to compensate for known risks assumed under that coverage, such as the estimated costs for prescription drugs covered under a policy² or for the implantation of a

2011) (“In general, health insurers enter into a contractual bargain with enrollees in which, in exchange for their service—assuming the risk of payment for enrollees’ future health care costs—they receive a ‘premium’, an up-front fee that represents the price of the insurance policy.”) (citing BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS, AND PROBLEMS*, 643 (6th ed. 2008)).

² TPPs maintain drug formularies, which is a list of medications approved for coverage under an insurance policy. Once a drug is placed on a formulary, the TPP is contractually obligated to its insurers to pay

prescription medical device. As the Eleventh Circuit Court of Appeals recently explained:

Because the value of the estimated claims drives the premium rate, the premium charged for a policy largely depends on the scope of the coverage under that policy. The broader the coverage offered—i.e., the more health care services indemnified by the insurer—the higher the premiums charged for that policy. In other words, covering more health care services creates a likelihood of more claims and, correspondingly, a greater projected claims value. The insurer will fund these higher costs through escalated premiums.³

The premium is essential to the insurer's goal of profitability. If calculated properly,⁴ from the insurer's

the drug's price anytime the drug is prescribed, regardless of its use. The TPP has to pay if the drug is prescribed for an FDA approved use or an off-label use. See *Ironworkers*, 634 F.3d at 1366.

³ See *id.* at 1365.

⁴ See *id.* ("Because of how paramount premiums are to their profitability, insurers engage in a technical actuarial analysis to price them. Through this ratemaking process, insurers aim to 'predict[] future losses and future expenses and allocat[e] those costs among the various classes of insureds.' Insurers predict losses on the basis of predicted claims costs. This prediction involves an assessment of (1) the likely number of times a covered event—e.g., a prescription of a covered drug—will occur and (2) the average cost of each covered event. If there is any uncertainty surrounding projected claims, insurers will raise the premium to

perspective, the insurer will collect more in premiums than it pays out in claims. However, when the claims exceed the insurer's projections, the insurer bears the risk of loss and, if those losses are due to an event, such as a medical device recall that impacts a significant number of insureds, the TPP will most certainly seek out ways to be made whole.⁵

II. Recovering Aggregate Losses

Traditionally, TPPs have sought to recoup their losses by asserting their rights to subrogation on a case-by-case basis. Under this approach, a TPP's liens are paid only if and when their insureds recover from their alleged tortfeasors, i.e., prescription drug and medical device manufacturers. TPPs are now trying to recover their losses in the aggregate pursuant to two different theories of *direct* liability, depending on whether prescription drugs or medical devices are involved. In the context of prescription drugs, the TPPs argue that, as a direct result of the drug manufacturer's fraudulent conduct—falsely touting the off-label benefits of a particular prescription drug—⁶ their insureds'

reflect that uncertainty. The final premium charged consists of this adjusted estimate plus administrative expenses projection that includes estimates for all those expenses that the insurance company charges that are not for claims, such as overhead.") (internal citations omitted).

⁵ See *id.*

⁶ The FDA prohibits the marketing of FDA-approved drugs for off-label uses – those for which the drug was not approved. See *Health Care Serv. Corp. v Olivares*, No. 2:10-CV-221-TJW-CE, 2011 WL 4591913, at *1 (E.D. Tex. Sept. 2, 2011). However, the practice of

treating physicians were induced to prescribe the drug more frequently when cheaper alternative options were available.⁷ Under this theory, the insurers seek to recover, in the aggregate, the difference between the amount actually

prescribing a drug for an off-label use “is both legal and commonplace in the medical community.” *Ironworkers Local Union 68*, 634 F.3d at 1356. This is because “[o]nce a drug has been approved by the FDA and placed on the market, physicians may prescribe it for any purpose. . . . Examples of ‘off-label’ uses include prescriptions of the drug for a condition not indicated on the label, treating an indicated condition at a different dose or frequency than specified on the label, or treating a different patient population than approved by the FDA.” *Id.* at 1356 n.4.

⁷ See, e.g., *Olivares*, 2011 WL 4591913; District 1199 Health & Welfare Plan v. Janssen, L.P., 784 F. Supp.2d 508 (D. N.J. 2011); *In re Yasmin & Yaz* (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., Nos. 3:09-md-02100-DRH-PMF, 3:09-cv-20071-DRH-PMF, 2010 WL 3119499 (S.D. Ill. Aug. 5, 2010); *In re Neurontin Mktg. & Sales Practices Litig.*, 677 F. Supp.2d 479 (D. Mass. 2010); Southern Ill. Laborers’ & Employers Health & Welfare Fund v. Pfizer, Inc., No. 08 CV 5175, 2009 WL 3151807 (S.D.N.Y. Sept. 30, 2009); Southeast Laborers Health & Welfare Fund v. Bayer Corp., 655 F. Supp.2d 1270 (S.D. Fla. 2009), *aff’d*, No. 10-13196, 2011 WL 5061645 (11th Cir. Oct. 24, 2011); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604 (D. N.J. July 10, 2009); *Ironworkers Local Union 68 v. Astrazeneca Pharms., LP*, 585 F. Supp.2d 1339 (M.D. Fla. 2008), *aff’d*, 634 F.3d 1352 (11th Cir. 2011); *In re Zyprexa Prods. Liab. Litig.*, 493 F. Supp.2d 571 (E.D.N.Y. 2007); *Prohias v. Pfizer, Inc.*, 490 F. Supp.2d 1228 (S.D. Fla. 2007); *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003).

paid and the amount that would have been paid for the less expensive alternative.

Conversely, when prescription medical devices are at issue, these same insurers allege that, as a direct result of a manufacturer’s wrongful conduct—designing, manufacturing, and selling allegedly defective devices—their insureds incurred physical and/or emotional harm, for which otherwise unnecessary medical treatment became necessary.⁸ TPPs seek to recover these “otherwise unnecessary” expenses, in the aggregate, directly from the device manufacturers.

TPPs are filing these aggregate recovery suits with increased frequency and most are doing so on behalf of a proposed class of similarly situated insureds, which, collectively, potentially covered tens of thousands of drug and medical device prescriptions. Since 2000, plaintiffs have filed more than twenty of these TPP direct liability actions in the federal courts, with nearly a dozen of those arising during or immediately following an MDL proceeding.⁹ And while the drug and device manufacturers have found some success in dismissing these claims on a Rule 12(b)(6) motion to

⁸ See *Kinetic Co. v. Medtronic, Inc.*, 672 F. Supp.2d 933 (D. Minn. 2009); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 484 F. Supp.2d 973 (D. Minn. 2007).

⁹ See e.g., Southeast Laborers Health & Welfare Fund v. Bayer Corp., No. 10-13196, 2011 WL 5061645, at *2 (11th Cir. Oct. 24, 2011); *Ironworkers Local Union 68*, 634 F.3d at 1357 n.9; *In re Yasmin & Yaz*, 2010 WL 3119499; *In re Neurontin*, 677 F. Supp.2d 479; *Kinetic Co.*, 672 F. Supp.2d at 939 n.2; *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 78 (E.D.N.Y. 2008); *In re Guidant Corp.*, 484 F. Supp.2d 973; *Desiano*, 326 F.3d 339.

dismiss for lack of Article III standing, the decisions are hardly uniform. Indeed, some federal courts have refused to reject these TPP claims at the initial pleading stage, which has ultimately resulted in a handful of million dollar settlements and one \$237 million judgment.¹⁰

III. Overview of Defense Strategies

Successful defense counsels have directed the courts' attention early in the litigation to the practical proof problems and inefficiencies that are involved with establishing Article III standing. By emphasizing the various considerations that may influence each insured's treating physicians' judgment in selecting a particular course of treatment for each individual patient, manufacturers have been able to demonstrate why generalized proof of injury and causation is inadequate to confer standing on these TPPs. Drug and device manufacturers should therefore insist that TPPs be required to present evidence of their alleged injuries on an individualized, insured-by-insured basis.

A. Legal Principles Of Article III Standing

The "irreducible constitutional minimum" of Article III standing requires every party invoking federal jurisdiction to bear the burden of establishing three essential elements to show that a justiciable case or controversy exists: (1) injury in fact, (2) a causal connection between the injury and the challenged conduct, and (3) redressability of the injury.¹¹ Described as more than mere pleading requirements, these elements are considered an "indispensible" aspect of every plaintiff's case and, therefore, must be supported "with the manner and degree of evidence required at the successive stages of the litigation."¹² This means that at the initial pleading stage, plaintiffs must allege enough *facts* to demonstrate a "plausible" entitlement to relief.¹³

To satisfy the first Article III standing requirement, plaintiffs must show that they suffered an "invasion of a legally protected interest" which is concrete and personal—not conjectural or hypothetical.¹⁴ Next, plaintiffs must show through their factual allegations that their alleged injuries are causally linked to the challenged conduct of the

¹⁰ See Thom Weidlich, *Lilly's \$4.5 Million Zyprexa Agreement With Health Providers Wins Approval*, BLOOMBERG, Jan. 12, 2012, available at www.bloomberg.com/news/2012-01-12/lilly-s-4-5-million-zyprexa-agreement-with-health-providers-wins-approval.html (last visited February 20, 2012). See also *In re Neurontin Mktg. & Sales Prac. Litig.* (Kaiser Found. Health Plan, Inc. v. Pfizer, Inc.), No. 04-cv-10739-PBS, 2011 WL 3852254, at *1-2 (D. Mass. Aug. 31, 2011).

¹¹ See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-562 (1992).

¹² *Id.* at 561.

¹³ See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007) ("a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.>").

¹⁴ *Lujan*, 504 U.S. at 560.

defendant.¹⁵ Their injuries cannot be the result of the “independent actions of some third party not before the court.”¹⁶ Finally, it must also be “likely” that the plaintiffs’ alleged injuries will be redressed if the court were to render a favorable decision.¹⁷

B. Aggregate Recovery Theory #1: Fraudulent Over-Pricing Of Prescription Drug Caused Injuries To TPPS

In an attempt to defeat drug manufacturers’ lack of standing arguments, TPPs argue that they have suffered a direct financial injury because they are the “purchasers” of fraudulently overpriced drugs.¹⁸ In this context, TPPs claim that they would not have purchased the drugs at issue had they or their insureds’ treating physicians not been misled by manufacturer’s off-label misrepresentations, especially when safer,

more effective, and cheaper alternatives were available on the market. Under this theory, TPPs contend that their economic injuries are sufficiently direct because they are unaffected by whether any given insured suffered harm through use of the product.¹⁹

Drug manufacturers have successfully defeated these “direct purchaser” allegations at the motion to dismiss stage by challenging (1) the TPPs’ assertion that they have alleged a sufficiently direct economic injury, and (2) whether the alleged injury was proximately caused by the manufacturer’s alleged misconduct. Success on either issue, or both, constitutes grounds for immediate dismissal of the action for lack of Article III standing in federal court.

1. Injury in Fact

As to the direct injury issue, defense counsel is encouraged to demonstrate the likelihood that the TPPs’ insureds, in most cases, received at least *some* medical benefit from using drug. This is because, unless TPPs can allege that the prescriptions they paid were “medically unnecessary or inappropriate” (as determined by the standards of practice in the medical profession), at least some federal courts have held that these TPPs have not incurred a plausible economic injury.²⁰ As the Fifth Circuit Court of

¹⁵ *Id.* To assert a federal RICO claim there must be some “direct relation between the injury asserted and the injurious conduct alleged. Thus, a plaintiff who complained of harm flowing merely from the misfortunes visited upon a third person by the defendant’s acts was generally said to stand at too remote a distance to recover.” *Holmes v. Sec. Investor Protec. Corp.*, 503 U.S. 258, 268-269 (1992).

¹⁶ *Lujan*, 504 U.S. at 560.

¹⁷ *Id.* at 561.

¹⁸ *See, e.g. In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004) (“it is well recognized that a purchaser in a market where competition has been wrongfully restrained has suffered an antitrust injury, and in this case, TPPs are such purchasers”); *Desiano*, 326 F.3d at 350 (noting that “several other courts” have recognized that TPPs are “buyers” of the prescription drugs they cover).

¹⁹ *See Desiano*, 326 F.3d at 349.

²⁰ *Ironworkers Local Union 68*, 634 F.3d at 1360, 1362-1364 (“To allow recovery based purely on the fact that the prescription was comparatively more expensive than an alternative drug—but otherwise safe and effective—would mean that physicians owe their patients a professional duty to consider a

Appeals recognized, “[m]erely asking for money does not establish an injury in fact.”²¹

To make this showing, TPPs will be forced to investigate why each of their insureds were prescribed the drugs they received—an endeavor their direct liability theory of recovery was designed to avoid. Since “[s]everal considerations shape the physician’s medical judgment, including both individual patient concerns and drug-specific information regarding the propriety of a drug’s use for treatment of a patient’s given condition,”²² each TPP should be required to demonstrate through individualized proof that its’ economic injuries were actually realized.²³ Certainly, no TPP can demonstrate an economic injury if it did not pay for a single off-label prescription or if the prescriptions it did pay for were medically necessary and appropriate.

drug’s price when making a prescription decision. No such duty exists.”); *see also* District 1199 Health & Welfare Plan v. Janssen, L.P., Nos. 06-3044(FLW), 07-2224(FLW), 07-2608(JAP), 07-2860(GEB), 2008 WL 5413105, at *8 (D. N.J. Dec. 23, 2008) (“[TPPs] do not plead a concrete financial loss in the form of overpayment, absent allegations that the drug was inferior on some level and worth less than what they paid for it.”).

²¹ *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir. 2002).

²² *Ironworkers Local Union 68*, 634 F.3d at 1362 (citations omitted).

²³ *See id.* at 1362-1363 (“The physician learns about a drug through multiple sources, only one of which might be the drug manufacturer’s promotions and literature. For instance, physicians typically obtain additional information about a drug’s putative uses from journals, meetings, and conventions.”).

In an effort to circumvent this individualized inquiry, TPPs assert that their economic injuries can be established through aggregate damages models showing that a manufacturer’s fraudulent marketing caused a “sharp increase” in the number of prescriptions that TPPs paid for.²⁴ And while courts have acknowledged that this approach has “strong intuitive appeal,” they also note that it still fails to indicate which doctor’s prescriptions were caused by the manufacturers’ alleged misconduct.²⁵ As one federal district court explained:

[T]rial courts have almost uniformly held that in a misrepresentation action involving fraudulent marketing of direct claims to doctors, a plaintiff TPP or class must show through individualized evidence that the misrepresentation caused specific physicians, TPPs, or insureds to rely on the fraud, and cannot rely on aggregate or statistical proof.²⁶

Defense counsel should therefore reject TPP attempts to use aggregate damages models as a substitute for establishing demonstrable economic injuries.²⁷

²⁴ *See, e.g., In re Neurontin*, 677 F. Supp.2d at 494; *In re Zyprexa*, 493 F. Supp.2d at 577-578.

²⁵ *In re Neurontin*, 677 F. Supp.2d at 494-495.

²⁶ *Id.* at 494 (citing *Southern Ill. Laborers’*, 2009 WL 3151807).

²⁷ *See In re Neurontin Mktg. & Sales Practices Litig.*, 754 F. Supp.2d 293, 310 (D. Mass. 2010) (holding that TPP plaintiffs do not allege an injury where they “have put forth no facts as to which, if any, doctors were tainted

2. Causation

Because TPP attempts at aggregate recovery present significant practical evidentiary proof obstacles, drug manufacturers have also successfully defeated these claims by arguing that the TPPs cannot establish proximate causation.²⁸ In this context, defense counsel should again emphasize the role of the treating physician in deciding which drugs to prescribe to which patients.²⁹ This way, manufacturers can illustrate how TPPs' alleged injuries are entirely dependent on the answers to the following insured-specific questions, none of which they will be able to address in the aggregate:

- For which medical condition(s) did each insureds' physician prescribe the drug;
- How many doses were prescribed for a particular insured, and how many of those were tied to alleged fraudulent marketing;³⁰
- Did any of the insureds' physicians receive the allegedly false information;³¹
- Did any of the insureds' physicians rely on the allegedly false information;³²

by misleading information like 'Dear Doctor' letters or other marketing material.”).

²⁸ See *id.* at 310-311.

²⁹ *In re Neurontin*, No. 1:04-cv-10981-PBS, 2011 WL 18882870, at *4 (D. Mass. May 17, 2011) (“[I]n order to differentiate those prescriptions that were caused by fraud from those that were attributable to non-fraudulent off-label marketing or other independent factors, a factfinder would have to perform a granular doctor-by-doctor analysis. This would be unmanageable” for purposes of class certification); *Southeast Laborers*, 655 F. Supp.2d at 1280-1281 (“There are many factors that a doctor may consider in determining what medication to administer to a given patient. Doctors are presumed to go beyond advertising medium and use their independent knowledge in making medical decisions.”); *In re Yasmin & Yaz*, 2010 WL 3119499, at *7 (“The role of the prescribing physician is problematic because it is an additional factor that could have contributed to the Plaintiff’s alleged injury (demonstrating remoteness).”).

³⁰ *Southeast Laborers*, 655 F. Supp.2d at 1280-1281 (noting that loss calculation would “require a determination as to how many doses a patient received, and whether or not the number of doses was tied to any fraudulent marketing.”).

³¹ *Southern Illinois Laborers*, 2009 WL 3151807, at *6 (holding that TPP plaintiffs’ theory of causation based on physician reliance on fraudulent marketing fails because “Plaintiffs do not cite a single instance in which a physician received the fraudulent information and decided to prescribe [the drug at issue] based on the information she received. Plaintiffs do not even explicitly allege the more general claim that physicians in general relied on Defendant’s misrepresentations. Accordingly, this causation argument fails as currently pled.”); *In re Schering-Plough Corp.*, 2009 WL 2043604, at *25 (noting that some doctors who prescribed the drug at issue “may have never received any information from [defendant].”); *In re Actimmune Mktg. Litig.*, 614 F. Supp.2d 1037, 1051-1052 (N.D. Cal. 2009) (holding that to establish causation, TPP “[p]laintiffs need to allege what specific information the individual plaintiffs or their physicians had about the drug”).

³² *Olivares*, 2011 WL 4591913, at *7 (“[Plaintiff] fails to allege that any doctors or

- Would any of the insureds' physicians, knowing the true risks and benefits associated with the drug, have prescribed the drug anyway;³³

other health care professional relied on any [defendant] misrepresentation promoting off-label use, as opposed to relying on the professional's own judgment and expertise, when prescribing the drugs."); *In re Neurontin*, 2011 WL 18882870, at *4 (noting that since the TPPs did not rely on the alleged misrepresentations themselves, "they would need to show that the prescribing physicians relied on fraudulent communications or suppression of evidence by [defendant]"); *Dist. 1199*, 784 F. Supp.2d at 524 ("Plaintiffs' allegations are too remote to satisfy the causation prong because they noticeably fail to allege that physicians . . . relied on any specific misrepresentation made by the Defendants."); *In re Neurontin*, 754 F. Supp.2d at 311 ("Because the Class TPP Plaintiffs have not directly relied on misrepresentations by defendants, and because they have presented no evidence as to how many or which physicians who prescribed [the drug] to their members relied on fraud, they cannot establish causation."); *So. Illinois Laborers'*, 2009 WL 3151807 ("Because the Plaintiffs do not expressly allege that physicians relied upon Defendant's misrepresentations, the Court finds that Plaintiffs have not alleged the necessary causal connection, and thus have not established Article III standing."); *Southeast Laborers'*, 655 F. Supp.2d at 1280-1281 ("Loss calculation necessarily would depend on whether or not a particular physician ever received or relied on [defendant's] allegedly fraudulent statements").

³³ *Southeast Laborers'*, 655 F. Supp.2d at 1280-1281 ("Loss calculation necessarily would depend on . . . whether or not a physician, knowing the risk vs. benefit of [the drug at issue], would still have used it during

- Did any of the insureds receive any medical benefit from using the drug;³⁴
- Which alternative drugs would the insureds' physicians have prescribed for each insureds' particular treatments;³⁵ and
- How much would those alternative drugs have cost?³⁶

By focusing the court's attention on these case-specific inquiries, drug manufacturers have been able to show why generalized proof cannot be used to show the existence of an economic injury that was proximately caused by the alleged misconduct.³⁷ Indeed, the

an operation."); *In re Actimmune Mktg. Litig.*, 614 F. Supp.2d at 1051-1052 (holding that to establish causation, TPP "[p]laintiffs need to allege . . . when the drug was prescribed, purchased and administered, and whether these actions would have been taken if not for the concealment/misrepresentations of facts made regarding the efficacy or leave thereof about [the drug at issue]").

³⁴ *Southeast Laborers'*, 655 F. Supp.2d at 1280-1281 (noting that loss calculation "would entail determining those patients who received [the drug at issue] who did not suffer any adverse reactions, and who might have actually been helped by use of the drug.").

³⁵ *Id.* (noting that loss calculation would "require speculation as to what alternative medications a particular physician would have ordered in a particular surgery").

³⁶ *Id.* (noting that loss calculation would "require speculation as to . . . how much th[e] alternative medication would have cost.").

³⁷ See *In re Neurontin*, 2011 WL 18882870, at *4 ("Aggregate proof has generally been held not to be sufficient to prove causation.") (citing *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 133-136 (2d Cir. 2010)); *Dist. 1199*, 784 F. Supp.2d at 524 ("Plaintiffs may

damages calculations under such an approach would be purely speculative and completely unmanageable.³⁸

3. Favorable Precedent for TPPs

Despite their successes, drug manufacturers remain vulnerable to

not aver ‘causation by way of generalized allegations and aggregate proof because there are numerous factors that could influence a physician when deciding to prescribe a certain drug.’); *In re Neurontin*, 754 F. Supp.2d at 310 (noting that while aggregate proof of causation “demonstrates the likelihood of some injury . . . it does not suffice to demonstrate the extent of harm caused by the fraud . . . Most courts have rejected such aggregate proof.”); *In re Schering-Plough Corp.*, 2009 WL 2043604, at *26 (“The TPP plaintiffs may not establish the requisite proximate cause through aggregate proof or generalized allegations of fraudulent conduct and resulting harm.”).

³⁸ See, e.g., *In re Yasmin & Yaz*, 2010 WL 3119499, at *7 (“To assess damages, the Court would have to delve into the specifics of each physician-patient relationship to determine what damages were caused by [the manufacturer’s] alleged fraudulent conduct, as opposed to what damages were caused by the physician’s independent medical judgment. After all, a physician is permitted to use prescription medication to treat conditions other than those stated on the labeling approved by the FDA when, in his or her best medical judgment, use of the drug will benefit the patient. . . . Attempting to ascertain damages in this scenario would result in the type of speculative damages analysis the direct proximate cause requirement is intended to prevent.”) (internal citations omitted); *Southeast Laborers*, 655 F. Supp.2d at 1280-1281 (noting that the “[c]alculation of [TPP] Plaintiff’s losses would be purely speculative.”).

adverse rulings where (1) state law standing and proximate cause standards are less stringent,³⁹ and/or (2) the insurers are able to adequately allege that they relied on a manufacturer’s alleged fraudulent representations. Under these circumstances, drug manufacturers could become exposed to potentially massive liability, especially if the prevailing TPP also represents a class of similarly situated insurers, all of whom provide coverage to thousands of affected individuals.

For example, the Second Circuit in *Desiano v. Warner-Lambert*, reversed the district court’s Rule 12(b)(6) dismissal of TPP plaintiffs’ New Jersey state-law claims because it found that the TPPs were the “direct victims” of the manufacturer’s fraudulent marketing campaign under New Jersey law.⁴⁰ The district court had previously concluded that TPPs could not establish proximate cause because, under Second Circuit precedent (*Laborers Local 17 Health & Welfare Benefit Fund v. Philip Morris, Inc.*⁴¹), this type of claim was “foreclosed.”⁴² Under that precedent, the

³⁹ Standing under state law is not equivalent to standing under federal law. See *In re Guidant Corp.*, 484 F. Supp.2d at 982 (“Standing under state law is not equivalent to standing under federal law.”) (citing *Metro. Express Servs., Inc. v. City of Kansas City*, 23 F.3d 1367, 1369 (8th Cir. 1994)); *Group Health Plan Inc.*, 86 F. Supp.2d 912, 917 n.2 (D. Minn. 2000) (explaining that Article III standing requirements are a “wholly separate determination” from state standing).

⁴⁰ *Desiano*, 326 F.3d at 351.

⁴¹ 191 F.3d 299 (2d Cir. 1999).

⁴² See *In re Rezulin Prods. Liab. Litig.*, 171 F. Supp.2d 299, 300-302 (S.D.N.Y. 2001) (citing *Laborers Local 17*, 191 F.3d 299).

Second Circuit held that TPP plaintiffs asserting a federal RICO violation could not establish proximate cause because their alleged injuries—the costs they incurred as a result of paying for the tobacco-related healthcare costs of their insureds as a result of the defendant tobacco companies’ alleged deception concerning the risks of smoking were:

entirely derivative of the harm suffered by plan participants as a result of using tobacco products. Without injury to the individual smokers, the Funds would not have incurred any increased costs in the form of payment of benefits, nor would they have experienced the difficulties of cost prediction and control that constituted the crux of their infrastructure harms. Being purely contingent on harm to third parties, those injuries are indirect.⁴³

Finding the claims in *Laborers Local 17* to be “closely analogous” to those asserted in *Desiano*, the district court granted the defendant manufacturer’s motion to dismiss.

In reversing the district court, the Second Circuit first noted that the relevant legal standard of proximate cause governing the case was not the law of RICO, as in *Laborers Local 17*, but rather the law of New Jersey, which the court suggested did not have “the relatively narrow directness requirements” as a claim under RICO.⁴⁴ But even assuming that the two proximate cause standards

were similar, the court also found the claims in *Laborers Local 17* to be “significantly different” from those in *Desiano*. Specifically, the court noted that:

[i]n the instant case . . . Plaintiffs allege an injury directly to themselves; an injury, moreover, that is unaffected by whether any given patient who ingested [the drug at issue] became ill. Plaintiffs’ claim is that the Defendants’ wrongful action was their misrepresentation of the [drug at issue’s] safety, and that this fraud directly caused economic loss to them as purchasers, since they would not have bought Defendants’ product, rather than cheaper alternatives, had they not been misled by Defendants’ misrepresentations. Thus, the damages—the excess money Plaintiffs paid Defendant for the [drug at issue] that they claim they would not have purchased ‘but for’ Defendants’ fraud—were in no way ‘derivative of damage to a third party.’⁴⁵

Concluding that “the insurers were directly harmed by the deception practiced on them,” the court established a precedent that TPPs have since continued to rely upon to justify their theory of aggregate recovery.⁴⁶

The more “atypical” means of defeating a drug manufacturer’s motion to dismiss, however, is for the insurer to

⁴³ *Id.* at 300-302 (citing *Laborers Local 17*, 191 F.3d 299).

⁴⁴ *Desiano*, 326 F.3d at 348-349.

⁴⁵ *Id.* at 349.

⁴⁶ *Id.* at 351 & n.9.

allege exactly what the manufacturers ask them to allege—facts sufficient to demonstrate that it relied on the manufacturer’s fraudulent representations and, as a result, suffered an economic injury.⁴⁷ In the Neurontin MDL, one such TPP, Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals (collectively “Kaiser”), did just that and ended up with a \$142 million jury verdict and a \$95.2 million restitution award.⁴⁸ In finding that Kaiser had standing to pursue its direct liability theory of recovery, the district court focused on the following key factual allegations:

- Kaiser utilized committees comprised of physicians that would determine which drugs would be placed on its formularies. Before a drug could appear on the formulary, the insurer would prepare a monograph on the drug, which would be reviewed by the committee;

- Kaiser added Neurontin to its formulary in 1994 with certain restrictions that limited its use.⁴⁹ As the drug’s approved uses expanded over time, Kaiser’s “Drug Information Service” (“DIS”) would prepare monographs summarizing all available studies and information related to the particular indications in question.
- Kaiser’s DIS would often solicit information from Neurontin’s manufacturer and, when responding to one of these requests, the manufacturer provided information that was “materially misleading.”
- Kaiser alleged that its DIS did not have access to studies known to the manufacturer that showed the drug’s negative or negligible effects.
- When news reports first surfaced revealing the manufacturer’s alleged fraudulent marketing campaign, Kaiser distributed information to physicians in an “attempt to correct and mitigate the effect of the misinformation and to reduce utilization of Neurontin for indications where the

⁴⁷ See *In re Neurontin*, 2011 WL 1882870, at *2-3.

⁴⁸ *In re Neurontin Mktg. & Sales Prac. Litig.* (Kaiser Found. Health Plan, Inc. v. Pfizer, Inc.), No. 04-cv-10739-PBS, 2011 WL 3852254, at *1-2 (D. Mass. Aug. 31, 2011). The court initially entered judgment on November 2, 2010, see *In re Neurontin Mktg. & Sales Prac. Litig.* (Kaiser Found. Health Plan, Inc. v. Pfizer, Inc.), 748 F. Supp.2d 34 (D. Mass. 2010), but later amended its findings to correct a citation error that it made in its original findings. See *In re Neurontin Mktg. & Sales Prac. Litig.* (Kaiser Found. Health Plan, Inc. v. Pfizer, Inc.), No. 04-cv-10739-PBS, 2011 WL 4026804, at *8 (D. Mass. Aug. 31, 2011).

⁴⁹ “Kaiser’s formulary restrictions are advisory to physicians, following the plan’s philosophy that physicians are in the best position to make individual prescribing decisions for patients. In order to prescribe ad drug that is either not on the formulary or restricted by the formulary . . . physicians need only check a box on the prescription form indicating that the drug is necessary for the care of a patient.” *In re Neurontin*, 677 F. Supp.2d at 486.

evidence suggested other treatments were of equal or greater efficacy.”

- Kaiser alleged that by June 2004, the number of Neurontin prescriptions written for its members had dropped by 34% since the news first broke about the manufacturer’s alleged misconduct.⁵⁰

The district court concluded that these alleged “activities represent direct interaction between Kaiser and [the manufacturer], providing the evidence of causation alluded to by the *Desiano* court.”⁵¹ The court also noted that the reduction in Neurontin prescriptions after Kaiser discovered the fraudulent conduct and took remedial action is “strong evidence of a causal link between [the manufacturer’s] misrepresentations and Kaiser’s alleged injuries.”⁵²

Although Kaiser was able to overcome the manufacturer’s motion to dismiss, its success certainly “represents the atypical situation.”⁵³ Indeed, as the above-referenced authorities suggest, the vast majority of TPPs cannot plead facts sufficient to establish standing and recover their losses in the aggregate. Instead, they must resort to recovering

their losses the traditional way—via subrogation.

4. Aggregate Recovery Theory #2: TPPs Incurred “Otherwise Unnecessary” Medical Expenses Due To Allegedly Defective Medical Devices

In addition to covering prescription drug costs, TPPs are also obligated to pay the costs associated with the implantation and monitoring of their insureds’ implantable prescription medical devices. And when products like pacemakers and defibrillators are involved—complex devices powered by an internal battery that naturally depletes over time—their coverage obligation also extends to routine device removal and replacement surgeries. What is less clear, however, is whether TPPs are financially responsible for the removal and replacement of a medical device that is subject to a voluntary, manufacturer-issued product advisory, *i.e.* a recall.

TPPs recently began testing their ability to sue medical device manufacturers directly in an effort to recover the costs they incurred to (1) remove and replace allegedly defective devices, and (2) provide medical treatment for the resulting physical and/or emotional harm caused to their insureds. Their theory is that these manufacturers fraudulently kept their products on the market, despite knowing of their defective nature, which in turn led doctors to select and insurers to pay for allegedly faulty devices.⁵⁴ To establish standing,

⁵⁰ See *In re Neurontin*, 677 F. Supp.2d at 486-487, 496-497. Kaiser also produced statements from physicians stating that “had they known of [the manufacturer’s] allegedly fraudulent marketing practices, they would have acted to change Neurontin’s status on the Kaiser formularies.” *Id.* at 487.

⁵¹ *In re Neurontin*, 677 F. Supp.2d at 496.

⁵² *Id.* at 497.

⁵³ *In re Neurontin*, 2011 WL 1882870, at *3.

⁵⁴ See *Kinetic Co.*, 672 F. Supp.2d 933; *In re Guidant Corp.*, 484 F. Supp.2d 973.

they extrapolate their perceived “direct purchaser” status from favorable decisions in the anti-trust and fraudulently over-priced prescription drug contexts to allege a direct financial injury by implication—once a purchaser, always a purchaser. From there, they contend that their economic injuries are sufficiently direct because they bore the “otherwise unnecessary costs” that would not have occurred but for the manufacturer’s misconduct.

A review of the applicable case law reveals a split of authority on the issue. From the defense perspective, *In re Guidant Implantable Defibrillators Products Liability Litigation* should be the controlling authority. In that case, the U.S. District Court for the District of Minnesota held that TPP plaintiffs lacked Article III standing on two separate grounds. First, the court held that TPPs did not allege sufficiently direct economic injuries because they provided no support for their assertion that they were “purchasers” of the devices at issue.⁵⁵ Specifically, the court noted that the insures (1) never agreed to pay for the devices based on their relationship with the manufacturer or representations the manufacturer made to it, (2) played no role in selecting which devices their insureds should receive, and (3) were contractually bound to pay for their insureds’ medical expenses, including those related to the recalled devices.⁵⁶ Since the TPPs had no direct relationship with the manufacturer, they could not

demonstrate that they were the direct “purchasers” of the recalled devices.⁵⁷

Second, the court determined that TPP plaintiffs lacked standing because no causal connection existed between their alleged injuries and the manufacturer’s alleged misconduct.⁵⁸ The court explained that:

[i]n essence, the TPP Plaintiffs allege that [the manufacturer] committed a tort on their insureds, causing injury and resulting in the injureds seeking medical treatment, which in turn caused economic harm to the TPPs because they were contractually obligated to pay for their injureds’ medical care. Without more, these claims are too speculative to establish a causal link between the alleged injury and the alleged misconduct.⁵⁹

Since the TPPs’ purported standing rested on the independent choices of doctors (who prescribed the devices) and their patients (who chose to receive the devices in lieu of other treatment options), the court granted the manufacturer’s motion to dismiss, without prejudice.⁶⁰

Less than three years later, another judge from the same district court confronted the TPP standing issue again in *Kinetic v. Medtronic, Inc.*, but declined to follow the *Guidant* rationale.⁶¹ Instead, the *Kinetic* decision focused

⁵⁷ *Id.*

⁵⁸ *Id.* at 984.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ 672 F. Supp.2d 933.

⁵⁵ *In re Guidant Corp.*, 484 F. Supp.2d at 983.

⁵⁶ *Id.*

entirely on the state of the “Nation’s present health care regime,” finding that it:

almost always requires third-party payors to shoulder a significant portion of the [insureds’] costs of medical services. To deny this fact, and to extract legal conclusions from the denial, denies reality, and real financial injuries occurring in the real world. . . .⁶²

By paying to remove and replace its’ insured’s recalled device, the court explained that the TPP in *Kinetic* incurred an “extra, early, and additional cost” which amounts to an “actual injury; there is nothing remote, speculative or hypothetical about it.”⁶³ It also noted that intermediaries should not be used by device manufacturers to shield themselves from liability to their “ultimate and true financial victim.”⁶⁴

As to causation, the court held that the role of the treating physician is not necessarily fatal to TPP standing so long as the insurer alleges facts “‘showing that [the physicians’] choices have been . . . made in such manner as to produce causation and permit redressibility of injury.’”⁶⁵ That showing was apparently made by the TPP in *Kinetic*: the devices at issue were purchased by hospitals, the hospitals were reimbursed by the TPPs, the manufacturer recalled the devices; and the TPPs covered the replacement expenses.⁶⁶ The TPP’s success on the

standing issue was short-lived, though, as the court subsequently dismissed all but one of its claims as preempted by federal law,⁶⁷ a defense brand-name prescription drug manufacturers are not entitled to assert.⁶⁸

5. Other Strategic Considerations: Class Certification

Another area of uncertainty for drug and device manufacturers is whether these types of TPP lawsuits should be certified as class actions, assuming they survive the manufacturers’ initial Article III standing challenge. In the prescription drug context, the court in *Neurontin* held that a class of TPP plaintiffs could become certified under Rule 23(b)(3) upon one of two showings.⁶⁹ First, if the proposed TPP class could demonstrate that the defendant manufacturer’s alleged fraudulent conduct caused each TPP to approve the drug’s use and reimburse for off-label indications in a manner that was different from what would have occurred

⁶² *Id.* at 940.

⁶³ *Id.*

⁶⁴ *Id.* at 941.

⁶⁵ *Id.* at 942-943.

⁶⁶ *Id.* at 943.

⁶⁷ *Kinetic Co. v. Medtronic, Inc.*, No. 08-CV-6062, 2011 WL 1485601 (D. Minn. Apr. 19, 2011). Relying on the express preemption provision of MDA, 21 U.S.C. § 360k(a), and the U.S. Supreme Court’s recent decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), medical device manufacturers have successfully argued that most state-law claims are preempted by federal law.

⁶⁸ See *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁶⁹ Success on either theory presumes that the TPP would have satisfied the initial certification requirements of FED. R. CIV. P. 23(a).

absent the fraud, class treatment would be appropriate.⁷⁰ To make this showing:

[TPPs] would have to present individualized evidence about what information [each TPP's drug approval committee] was exposed to regarding [the drug at issue] and how the absence of fraudulent information would have altered [the drug at issue's] placement within [the TPP's] formulary and how that alternative classification of [the drug at issue] would have saved the TPP money.⁷¹

The *Neurontin* court also noted that, due to the "heterogeneity" of each TPPs' formularies, such a showing cannot be made through generalized proof.⁷²

Second, if TPP plaintiffs cannot establish that they directly relied on the manufacturer's alleged misrepresentations, they would need to show that their insureds' prescribing physicians relied on the misrepresentations.⁷³ This approach would require each TPP to conduct a "granular doctor-by-doctor analysis," that the TPPs aggregate liability theory sought to avoid.⁷⁴ Thus, even after the initial pleadings stage, Defense counsel should continue to insist on individualized proof of reliance and causation in order to defeat liability and, if necessary, to minimize the scope of potential damages.

III. Conclusion

Although federal courts have been reluctant to allow TPPs to proceed with a direct liability theory of aggregate recovery, prescription drug and medical device manufacturers remain susceptible to adverse dispositive motion rulings, class certification, and even multi-million dollar judgments. Given this reality, defense counsel are encouraged to keep abreast of the landscape of this type of TPP litigation and become familiar with the strategies manufactures are utilizing to dispose of these actions in their infancy. If drug and device manufacturers are ultimately successful in their attempt to halt this form of aggregate recovery at the initial pleadings stages, TPPs will have no choice but to return to the conventional method of recovering liens on a case-by-case basis via subrogation.

⁷⁰ *In re Neurontin Mktg. & Sales Practices Litig.*, 257 F.R.D. 315, 333 (D. Mass. 2009).

⁷¹ *Id.*

⁷² *Id.*

⁷³ *In re Neurontin*, 2011 WL 1882870, at *4.

⁷⁴ *Id.* at *5.