In the

United States Court of Appeals

For the Seventh Circuit

No. 17-1483

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER and TEAMSTERS HEALTH SERVICES AND INSURANCE PLAN LOCAL 404,

Plaintiffs-Appellants,

v.

ABBOTT LABORATORIES and ABBVIE INC.,

Defendants-Appellees.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 13 C 5865 — **Sara L. Ellis**, *Judge*.

ARGUED SEPTEMBER 12, 2017 — DECIDED OCTOBER 12, 2017

Before EASTERBROOK, KANNE, and WILLIAMS, *Circuit Judges*.

EASTERBROOK, *Circuit Judge*. The Food and Drug Administration has approved the use of Depakote (divalproex sodium) to treat seizures, migraine headaches, and some conditions associated with bipolar disorder. Physicians are free to prescribe it to treat other conditions, called off-label uses,

but a drug's manufacturer can promote it only as suitable for uses the FDA has found to be safe and effective. Abbott Laboratories, which makes Depakote, encouraged intermediaries to encourage Depakote's off-label uses while hiding its own involvement. This promotion, for conditions including schizophrenia, dementia, and attention deficit hyperactivity disorder (ADHD), was detected, and prosecution followed. In 2012 Abbott pleaded guilty to unlawful promotion and paid $1.6 billion to resolve the criminal case and settle *qui tam* actions that had been filed against it under the False Claims Act, 31 U.S.C. §§ 3729–33. The next year saw the transfer of Depakote sales in the United States to AbbVie, a fraternal corporation, but for simplicity we ignore AbbVie.

Two welfare-benefit plans that paid for some of Depakote's off-label uses filed this suit in 2013 seeking treble damages under the civil-liability provision in the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1964. They asked the district court to certify a class comprising all third-party payors of drug expenses. (The parties call them TPPs; we prefer Payors.) The district court dismissed the suit as untimely. 64 F. Supp. 3d 1146 (N.D. Ill. 2014). Civil RICO actions must be commenced within four years after injury was or should have been known. *Agency Holding Corp. v. Malley-Duff & Associates, Inc.*, 483 U.S. 143 (1987); *Rotella v. Wood*, 528 U.S. 549 (2000). The judge observed that off-label promotion began in 1998 and the first *qui tam* suit was filed in 2007. But the *qui tam* suits began under seal, which lasted until 2011, and alleged that Abbott had concealed its role in the off-label promotions. These considerations led us to remand so that the parties could explore through discovery when a reasonable Payor first should have understood that it was paying for drugs that had been prescribed in response

to an undercover marketing campaign. *Sidney Hillman Health Center of Rochester v. Abbott Laboratories, Inc.*, 782 F.3d 922 (7th Cir. 2015).

Discovery did not occur. Nor was a class certified. Instead the district judge dismissed the complaint on a different ground, this time ruling, see 192 F. Supp. 3d 963 (N.D. Ill. 2016), that the plaintiffs could not hope to show proximate causation, another of RICO's requirements. See, e.g., *Hemi Group, LLC v. New York City*, 559 U.S. 1 (2010); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006); *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992). The judge observed that the improper marketing was directed at physicians and concluded that tracing loss through the steps between promotion and payment would be too complex.

To the extent the district judge believed that it is never permissible to base RICO damages on injury to one person caused by wrongs against another, the decision conflicts with *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008). The plaintiffs in *Bridge* alleged that defendants had conspired to submit multiple bids in an auction whose rules limited to one the number of bids allowed to any person or group. Plaintiffs contended that the extra bids did not harm the auctioneer but diminished their own chances of profitable transactions. The Court held that a RICO recovery is possible when a wrong against A directly injures B. Our plaintiffs say that their situation is identical: unlawful sales tactics don't injure doctors, who do not use or pay for the drugs they prescribe, but directly injure Payors. The Supreme Court several times has stated in RICO litigation that the initially injured person can recover, and indeed that "[t]he general tendency of the law, in regard to damages at least, is not

to go beyond the first step," *Holmes*, 503 U.S. at 271–72, quoted with approval in *Hemi Group*, 559 U.S. at 10. Plaintiffs insist that Payors are the "first step" and so are entitled to proceed with the suit.

Payors part with money, to be sure, but it is not at all clear that they are the initially injured parties, let alone the sole injured parties.

The relators in the *qui tam* actions alleged, as did the criminal prosecutor, not simply that Abbott promoted Depakote for unapproved uses, but also that Depakote was not effective, or even was harmful (compared with placebos or other drugs), for some of those uses. Abbott commissioned studies that it hoped would show the benefits of Depakote for additional maladies, and the relators asserted that one of these studies was discontinued because Depakote was harming the patients, while the result of another was suppressed because it showed no benefit compared with a placebo. According to the *qui tam* suits, however, Abbott went right on marketing Depakote for off-label uses. This description of the conduct implies that the Payors are not the only, or even the most directly, injured parties.

Patients suffer if they take Depakote even though it is useless to them and may be harmful. They suffer adverse health effects if Depakote (a) aggravates their medical conditions, (b) produces side effects not justified by medical benefits, or (c) dissuades them from taking drugs that *would* alleviate their conditions. Many patients also incur financial loss. Filling prescriptions usually entails out-of-pocket costs to patients even when health insurance or welfare-benefit plans cover most of the expense. The patients' health and financial costs come first in line temporally; that pharmacies

then send bills to Payors, which cover the remainder of the expense, does not make those Payors the initial losers from the promotional scheme to which Abbott pleaded guilty.

Physicians also may lose, though less directly. People with medical conditions such as schizophrenia or ADHD want help. If a physician prescribes an ineffective medicine and so does not provide that help, patients may turn elsewhere. Physicians affected by off-label promotions thus may lose business and revenue.

Plaintiffs contend that Payors bear the *principal* costs of off-label promotions, because they pay for most of the cost of the drugs, but comparing the patients' health costs (and out-of-pocket co-pays) with the Payors' costs may be difficult.

And those difficulties are compounded by other possibilities.

First, some off-label uses of Depakote may be beneficial to patients. That makes it hard to treat all off-label prescriptions as injury to the Payors, which if they did not pay for Depakote would have paid for some other drug that physicians would have prescribed in lieu of Depakote—a drug that might have helped patients less yet cost the Payors more. It would not be proper to calculate damages by assuming that all off-label prescriptions are improper.

Second, whether or not any given off-label prescription for Depakote helped the patient (compared with another drug), some physicians were apt to write such prescriptions whether or not Abbott promoted off-label uses. We know that the number of off-label prescriptions grew once Abbott began its campaign, but off-label prescriptions did not start from zero. To calculate damages it would be necessary to

determine the volume of off-label prescriptions that would have occurred in the absence of Abbott's unlawful activity. That may not be an easy task.

Third, some physicians doubtless were proof against the campaign of disinformation. They may not have changed their prescribing practices at all, or they might have changed them but done so in response to information that Abbott did not influence. The medical literature contains not only double-blind clinical studies but also case studies and even anecdotes that affect physicians' prescribing practices. For some physicians, these may have dominated over anything Abbott did. Disentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices would be difficult—much more difficult than following the one-step causal link in *Bridge*.

Plaintiffs tell us that they can estimate the effects of Abbott's promotion by using a regression analysis. If the intensity of Abbott's efforts differed in different parts of the country, it may be possible to see how much additional Depakote was prescribed in the more promotion-intensive areas. This would enable a statistical inference linking the volume of off-label sales to the amount of promotion and could in principle address the problems that we labeled "second" and "third" above.

But there are some big ifs. *Did* the intensity of Abbott's promotion differ regionally? If yes, how much of the difference was offset by information that flowed from one region to another through medical meetings or publications? Did any remaining difference affect Depakote's sales for off-label uses by enough to allow a statistically significant inference, or did other things, such as word of mouth in the profession,

and published reports, make the national experience more uniform? We asked plaintiffs' counsel at oral argument whether a study of this kind is in the record. Counsel said no and asserted that this is because the case was dismissed on the complaint—yet, if such a study had been conducted, it could have been attached to the complaint or submitted any time after the suit's filing. We also asked whether such a study has been published. Again the answer was no. The absence of data leaves a serious problem in showing plausible causation, which is required even at the complaint stage. And notice that the only kind of problems a regression analysis could address would be those we labeled "second" and "third" above. It would not address the question whether patients suffered medical losses or out-of-pocket costs via co-pays, or whether physicians lost business by prescribing an ineffective or harmful drug, or what to do about patients whose off-label use of Depakote made them healthier.

Hemi Group rejected, as too indirect or contingent, a claim by New York City based on a seller's failure to file reports that would have helped the City collect taxes. The immediate cause of loss was buyers' failure to pay those taxes, the Court observed, and the failure to file reports just took away one tool for collection. The causal chain in our case is longer than the one *Hemi Group* deemed too long. The immediate effect of wrongful off-label promotion is on physicians' conduct. Some physicians will change, to some degree, which drugs they prescribe for what conditions; some patients will be affected for good (health benefits) or ill (health and financial losses) by the physicians' decisions; finally some of the financial costs will be borne by Payors, who are made worse off to the extent Depakote is more expensive than the drug that otherwise would have been prescribed (whatever drug

that should have been) but better off to the extent that Depakote is cheaper than that alternative drug.

Five other courts of appeals have considered the extent to which Payors can recover under RICO for wrongs committed while marketing pharmaceuticals. *Sergeants Benevolent Association Health and Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71 (2d Cir. 2015), and *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121 (2d Cir. 2010), hold that there are so many layers, and so many independent decisions, between promotion and payment that the causal chain is too long to satisfy the Supreme Court's requirements. Two other circuits agree and deem this so straightforward that they have issued nonprecedential decisions. *United Food & Commercial Workers Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255 (9th Cir. 2010); *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401 (11th Cir. 2011). See also *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP*, 634 F.3d 1352, 1370 (11th Cir. 2011) (Martin, J., concurring) (agreeing with the Second Circuit).

In re Avandia Marketing, Sales Practices & Product Liability Litigation, 804 F.3d 633 (3d Cir. 2015), agrees with the Second Circuit's position as a rule but held that recovery under RICO is possible when misrepresentations are made directly to Payors, leading them to add certain drugs to their formularies, which means that they pay more per prescription than they would otherwise. Finally, *In re Neurontin Marketing & Sales Practices Litigation*, 712 F.3d 21 (1st Cir. 2013), while agreeing with the Third Circuit about the consequences of misrepresentations directly to Payors, implies disagreement with the other four circuits about the possibility of Payors' recovery for misrepresentations made to physicians. The

implication of *Neurontin* may be short of a holding, but to the extent there is a conflict the Second Circuit has this right. Like it, we hold that improper representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence. Public prosecution avoids these problems, so Abbott's criminal conviction and $1.6 billion payment were the proper remedies.

AFFIRMED