No. 10-1173

IN THE
Supreme Court of the United States

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED, ET AL.,

Petitioners,

v.

ELI LILLY AND COMPANY,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF FOR LABOR HEALTH ALLIANCE AND COMMUNITY CATALYST, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTERESTS OF *AMICI CURIAE*[1]

Amicus curiae Labor Health Alliance is a group formed by New York metropolitan area health and welfare funds in 1996 to increase dissemination of information on resources, networking and collective purchasing opportunities. Membership includes public and private sector health, welfare and pension funds, collectively representing more than one million covered lives.

The LHA mission is to provide an opportunity for collectively bargained, public and private sector employee benefits funds with their participating members, unions and employers, to purchase quality, cost effective health care services through an independent, not for profit cooperative. LHA acts as an advocate and educational resource for benefit funds and their enrollees.

Amicus Curiae Community Catalyst, Inc. is a national non-profit organization committed to building consumer and community voice in health care. In collaboration with local, state and national advocates and supporters, Community Catalyst advances improvements in health care policies and programs at the federal level and in over forty states. Through its Prescription Access Litigation,

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[1] Counsel of record for all parties received a letter indicating the intent to file this *amici curiae* brief at least 10 days prior to the due date of this brief pursuant to Supreme Court Rule 37. All parties consent to the filing of this brief. *Amici curiae* affirm that no counsel for a party authored this brief in whole or part, or made a monetary contribution specifically preparation or submission of this brief.

LLC project ("PAL"), it seeks to promote expanded access to needed medicines while also challenging deceptive, fraudulent, or illegal promotional drug industry practices that inflate drug costs, through litigation or other legal action. PAL has built a nationwide coalition of over 130 organizations in 36 states and the District of Columbia, with a combined membership of over 13 million people, comprised of consumers, seniors, health care advocacy organizations, labor unions, health plans, and union benefit funds. PAL has facilitated its coalition members' active participation in over 30 class action lawsuits, including litigation concerning the unapproved use promotion of Seroquel, Zyprexa, and Neurontin.

SUMMARY OF THE ARGUMENT

Amici curiae submit this brief to highlight particular problems raised by the Court of Appeals' decision that merit this Court's review. Specifically, the blinkered view of causation embodied in the Court of Appeals' decision erects a structural barrier to third party payers' ability to recoup harm they suffer as a result of health care fraud committed by pharmaceutical marketers. Because prescription drugs are purchased by petitioners and *amici curiae* and their members—but are chosen by physicians—pharmaceutical manufacturers largely direct their marketing efforts to doctors and patients, not third party payers. Hence, pharmaceutical marketing fraud targets individuals who have the power to make choices among competing products but impacts (to the greatest degree) entities without that power that foot the bill. This unconventional market

dynamic lends itself to third party payers absorbing the costs of marketing fraud directed to and relied on by others.

The Court of Appeals' decision incorrectly replaces the element of RICO causation with a requirement of first party reliance in conflict with *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008). *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) ("[c]rucially, the TPPs do not allege that *they* relied on Lilly's misrepresentations-the misrepresentations at issue were 'directed through mailings and otherwise at doctors'") (citation omitted). This Court's *Bridge* decision correctly emphasized that a RICO plaintiff need not demonstrate its own reliance in order to establish his or her claim. 553 U.S. at 648 ("[i]f petitioners' proposed requirement of first-party reliance seems to come out of nowhere, there is a reason: Nothing on the face of the relevant statutory provisions imposes such a requirement"). What is necessary, as the United States Court of Appeals for the Seventh Circuit concluded when *Bridge* was remanded from this Court, is a showing that the harm alleged was a reasonably foreseeable result of the conduct. *BCS Servs., Inc. v. Heartwood 88, LLC*, __ F.3d __, __, Nos. 10-3062, 10-3068, 2011 WL 1045853, *3-10 (7th Cir. Mar. 24, 2011).

ARGUMENT

I. PRESCRIPTION DRUG BUYERS DO NOT CHOOSE AMONG AVAILABLE THERAPY; DOCTORS DO, SO MANUFACTURERS DIRECT THEIR MARKETING TO DOCTORS

In the United States, pharmaceuticals cannot be marketed or sold without approval by the Food and Drug Administration ("FDA"). 21. U.S.C. §§ 355(a), (d). FDA requires a drug's manufacturer to demonstrate that the drug is safe and effective for each indication sought. FDA does not study or test drugs. Rather, FDA requires manufacturers to include "full reports of investigations which have been made to show whether or not such drug is safe or use and whether or not such drug is effective in use" as part of New Drug Applications ("NDA"). 21 U.S.C. § 355(b)(1)(A). FDA reviews the information from the manufacturer and decides whether the drug will be approved to treat a particular indication.

FDA approves drugs for use in treating a particular disease state or condition, referred to as the "indication." 21 U.S.C. §§ 352, 355(d). A manufacturer must provide safety and efficacy information for each desired indication. For each indication approved, the dosage that FDA determines to be safe and effective is given in the labelling information. A drug's label, included as an insert in the drug's packaging, lays out the approved indications and dosages. 21 U.S.C. §§ 352, 355(d).

Once a drug has been approved, "FDA has limited resources to monitor the 11,000 drugs on the market,[ ] and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) (footnote omitted). FDA's primary tool for protecting patients is requiring the manufacturer to change its product label to reflect any increased risk of various side effects or interactions. *See* 21 C.F.R. § 201.57(3). A manufacturer may, of its own accord and without FDA approval, change a label to reflect new safety information. In fact, a manufacturer is responsible at all times to ensure that a drug's label "remain[s] adequate as long as the drug is on the market." *Wyeth*, 129 S. Ct. at 1198 (citations omitted).

FDA provides guidance for the marketing and promotion of pharmaceuticals. A manufacturer seeking to promote an approved drug for uses other than those listed on the approved label must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication). Unapproved uses for drugs have, by definition, not been subject to FDA scrutiny, so there is no assurance that they are safe and effective for treatment.

Physicians may prescribe drugs for unapproved uses. Yet out of recognition of the potential conflict between what is best for the patient and what is best

for the pharmaceutical manufacturer, FDA has promulgated regulations restricting how drug companies may promote approved drugs. 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81.

A manufacturer illegally "misbrands" a drug if the drug's labelling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Any person that engages in such misbranding "shall be imprisoned for not more than one year or fined not more than $1,000, or both." 21 U.S.C. § 333. Unless a supplemental NDA has been filed seeking a new indication, unapproved use information can only be distributed at the request of a health care provider. 21 U.S.C. §§ 360aaa-366. There is a disturbing recent trend of misbranding convictions of large pharmaceutical manufacturers involving unapproved use promotion.[2]

Upon receiving FDA approval, manufacturers, motivated by a desire to maximize profits, actively promote use of new drugs in order to influence physician prescribing patterns. *See* Shoo K. Lee, *Re-examining Our Approach to the Approval and Use of New Drugs*, 174(13) Canadian Medical Journal 1855 (June 20, 2006). Drug companies market products

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[2] *See, e.g.*, press releases regarding settlement of charges by the DOJ involving Neurontin (http://www.usdoj.gov/opa/pr/2004/May/ 04_civ_322.htm), Oxycontin http://www.usdoj.gov/usao/ vaw/press_releases/purdue_frederick10may2007.html), and Genotropin (http://boston.fbi.gov/dojpressrel/ pressrel07/ kickbackplea040207.htm).

through "detailing" physicians about the new drug's benefits over other drugs.

Detailing occurs when pharmaceutical manufacturers send sales representatives for "face-to-face advocacy of a product by sales representatives who visit doctors' offices and hospitals." *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 71 (1st Cir. 2008). Detailing "focuses primarily on brand-name drugs that are entitled to patent protection. Once a patent expires, competitors may obtain approval to sell generic bioequivalent versions of the drug, which are equally effective for most patients but usually much less expensive than their brand-name counterparts." Detailing drives profits. As the *IMS Health* Court observed:

> Pharmaceutical detailing has pushed the art of marketing into uncharted waters. In the service of maximizing drug sales, detailers use prescribing histories as a means of targeting potential customers more precisely and as a tool for tipping the balance of bargaining power in their favor. As such, detailing affects physician behavior and increases the likelihood that physicians will prescribe the detailers' (more expensive) drugs.

IMS Health, 550 F.3d at 54.

Patients and physicians alike are optimistic about the promises a new drug brings. There is always a hope that new drugs will be better than old drugs, provide more relief than old drugs, or be safer

than old drugs. *See* Fuson F. Gonul et al., *Promotion of Prescription Drugs and Its Impact on Physicians' Choice Behavior*, 65 J. Marketing 79 (July 2001). Pharmaceutical companies prey on this hopefulness, saturating physicians and patients alike with positive information about the drug. *See* Ernst R. Berndt et al., *An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts*, 5 J. Mental Health Policy Econ. 3 (2002) ("Berndt, *Diffusion*"). Between physician and patient optimism and the flood of favorable information from manufacturers, tremendous pressure is placed on payers and insurers to cover new drugs. This is particularly true for mental health drugs, like Zyprexa, where the condition being treated is so devastating and difficult to treat.

Prescription drugs—their development, use, and cost—are unlike traditional commodities. First, only with physician approval and monitoring can a patient use a prescription drug. Second, most prescription drug costs are paid by third party payers, not patients. Third party payers face severe difficulty in placing restrictions on access to healthcare, particularly where mental health treatment is at issue. This dynamic—where neither the patient nor the payer control which drug will be prescribed or used—results in a system completely reliant on the truthfulness of pharmaceutical manufacturers for the proper, safe and efficient utilization of healthcare.

Physicians are rational decision-makers, looking to choose the best course of treatment for their patients. In making such decisions, physicians rely

on a backdrop of information about drugs and treatments, informed by multiple sources. These include pharmaceutical labels, medical and scientific journal articles, continuing medical education, and sales representatives. Yet all of these sources of information are influenced, if not directly controlled, by the drug's manufacturer: the label is approved by the FDA based on information from the manufacturer; medical and scientific journal articles are frequently ghostwritten by the manufacturer;[3] continuing medical education events are often company-sponsored and include speakers recruited and paid by the manufacturer; and sales representatives engage in highly scripted dialogues with physicians, under pains of losing their jobs should they deviate from the information provided by the manufacturer.

Pharmaceutical manufacturers recognize that prescribing habits are influenced by physicians' interactions with their colleagues and actively recruit "thought leaders" to help promote their drug through speaking and funded research. *See* Adriane Fugh-Berman and Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors*, 4(4) PLoS Medicine 0621 (April 2007). Drug-sponsored lectures, including those by "thought leaders," are two-and-a-half to three times more likely to highlight the sponsor's drug (and to position the competitors' drugs in a neutral or negative light)

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[3] *See* "Eli Lilly 'Ghostwrote' Articles to Market Zyprexa, Files Show", Bloomberg News, June 12, 2009, available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aVvfe.v1k_VY.

than are non-commercially sponsored lectures. *See* A. Wazana, *Physicians and the Pharmaceutical Industry*, 283 JAMA 373-380 (2000). Physicians who attend sponsored lectures may increase the number of prescriptions they write based on their respect for the "thought leader" discussing the drug. Studies demonstrate that although physicians may be unaware or may deny the influence, attendance at commercially-sponsored medical education activities increases the number of prescriptions written for the sponsor's drug. *See* Jason Dana, *A Social Science Perspective on Gifts to Physicians From Industry*, 290(2) JAMA 252 (July 9, 2002).

Physicians are highly susceptible to marketing by pharmaceutical manufacturers about their products, as respondent's expert, Dr. Ernst Berndt, acknowledges. *See* Berndt, *Diffusion*. Dr. Berndt notes the spread of information about a new drug or treatment depends partly on direct recent experiences with the medication, but also on pharmaceutical manufacturers' marketing efforts and interactions with colleagues. Pharmaceutical manufacturers spend significant time and monetary resources marketing to physicians, particularly following initial and subsequent FDA approvals. Physicians value these efforts, it seems, as it reduces the costs of obtaining information about treatments. *See id.* This reliance on pharmaceutical marketing —spread out through sales representatives, "thought leaders", continuing medical education events, ghost-written journal articles, and company-sponsored research—frequently results in circumstances like those shown here, where an inferior drug gains and retains more of the market than it otherwise would.

See Ernst R. Berndt et al., *Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs*, 51(2) J. Indus. Econ. 243 (June 2003). According to Berndt, "Greater marketing occurs regardless of whether superior quality manifests itself through the product's effectiveness and/or its side effect profile." Berndt, *Diffusion*, at 15.

Very few Americans pay completely out-of-pocket for prescription drugs. Instead, the vast majority have some form of insurance—public or private—that covers a significant portion of their healthcare and prescription drug costs. These payers face substantial pressure to make available a wide variety of treatment and drugs and to otherwise step out of the way of physician decision-making about healthcare.

Many healthcare providers utilize the services of a pharmacy benefit manager ("PBM") to manage their prescription drug benefit. PBMs act as administrators of the benefit and manage approximately three-quarters of all outpatient prescription drug claims in the United States. These entities do not influence the prescribing of particular drugs by physicians and have no control over the drugs used. Instead, PBMs act as middle-men, ensuring prescriptions are filled and paid for.

Formularies are lists of drugs covered and thus reimbursable by a specific health benefit provider or plan and are typically crafted by the provider's PBM. Formularies can be used in some circumstances to limit use of certain drugs or encourage use of others

by modifying the amount of a patient's co-pay or share of the costs. The most common example of this is generic substitution: because generic drugs are almost universally cheaper than their branded equivalents, formularies typically encourage use of generics (where available) by reducing a patient's share of the costs for them. Formularies cannot prevent physicians from prescribing any particular drug, however, and thus can only control, to some degree, what portion of the cost of the treatment will be borne by the health benefit provider and what portion will be borne by the patient.

PBMs use a pharmacy and therapeutics committee ("P&T"), which may include physicians and pharmacists, to determine what drugs to place on formulary. In deciding what to include, P&T committees do not conduct their own studies and instead rely on publicly available information about the drug, including the drug's label, clinical studies, and medical and scientific literature. This publicly available information is derived from the drug's manufacturers – particularly at and for years following the launch of the drug as the manufacturer is the only entity with complete information about the drug and its safety and efficacy. Typically, P&T committees include on formularies all or nearly all products approved by the FDA. This is especially so where mental health drugs are concerned: formularies make such drugs available, on the same basis, to their beneficiaries.

While formularies are used in an effort to control costs, they have little power to fight the high price of drugs or restrain spending on them. Because third

party payers are under tremendous pressure, from consumers, advocacy organizations, and competitors, including public payers such as Medicaid, to offer access to most drugs, regardless of cost, additional cost control measures are difficult. Instead, health benefit providers must rely on the rational decision-making of physicians in determining the best courses of treatment for patients, which, in turn, relies completely on the truthfulness of manufacturers in conveying information about their products.

The market dynamics in the pharmaceutical industry, as detailed above, are such that the person making the choice of therapy—the doctor—has no cost containment interest, while the entity paying the bill—the third party payer—has no say in the appropriate selection of product. Hence, pharmaceutical manufacturers focus their marketing efforts on doctors, not payers.

II. RICO CAUSATION REQUIRES A SHOWING OF FORESEEABLE HARM, NOT FIRST-PARTY RELIANCE

The Court of Appeals incorrectly relied on the Supreme Court's partial opinion in *Hemi Group, LLC v. City of New York*, 130 S. Ct. 983 (2010) while ignoring the holding of *Bridge*. In *Bridge*, the unanimous Court reasoned that the plaintiff's alleged injury was the "result of [the defendant's] fraud" because "[i]t was a foreseeable and natural consequence of" the defendant's scheme. 553 U.S. at 658 (emphasis added). In *Hemi*, the plurality opinion disagreed that "RICO's proximate cause

requirement [should] turn on foreseeability," without even mentioning *Bridge*. *Hemi*, 130 S. Ct. at 991. However, a plurality opinion cannot alter this Court's holding in *Bridge*. Justice Ginsburg, who provided the necessary fifth vote supporting the Court's judgment in that case, in her concurring opinion, expressly *declined* to "subscrib[e] to the broader range of the [plurality's] proximate cause analysis," including its views on foreseeability. *Id.* at 995 (Ginsburg, J., concurring in part and concurring in the judgment). And Justice Breyer's dissent, joined by two other justices, advocated the broader foreseeability standard of *Bridge*. Only four of the Court's eight justices in *Hemi* (Justice Sotomayor did not participate) subscribed to a higher proximate cause threshold than that enunciated in *Bridge*. Because Justice Ginsburg "concurred in the judgment[] on the narrowest ground[]," her "position" is best viewed as the "holding of the Court" in *Hemi*. *Marks v. United States*, 430 U.S. 188, 193 (1977) (internal quotations marks omitted).

The *Hemi* plurality opinion thus could not—and did not—overrule *Bridge's* holding that the requirement of proximate cause is met when, as here, the plaintiff's injury is "a foreseeable and natural consequence of" the defendant's misconduct. *Bridge*, 553 U.S. at 658. Judge Posner, writing for a Seventh Circuit panel on remand from this Court correctly held that "once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation."

BCS Services, 2011 WL 1045853, at *8. The Seventh Circuit held:

> Notwithstanding the existence of an important but neutral middleman in the chain of causation, the plaintiff bidders' injuries could nonetheless have been proximately caused by the remote bid riggers: . . . defendants' aim was to obtain a larger share of tax liens. The larger share came from other bidders, the bidders we're calling one-armed. The *only* injury was to those bidders, who included the two plaintiffs.... It was a matter of indifference to the County who bought the tax liens, for whoever it was would have to pay the County taxes on the properties subject to the liens. The bidders were thus the only victims of the fraud – and the plaintiffs are one-armed bidders.

BCS Servs., 2011 WL 1045853, at *6. (emphasis in original).

Third party payer victims of pharmaceutical fraud occupy the same role as the *BCS Services* "one-armed bidders." The prescribing doctors whom respondent argues fatally interrupt the causal chain are indifferent to cost, just like the County in *BCS Services*. Respondent's two-step fraud was directed to first getting approval for Zyprexa, however narrow an indication, which gained Zyprexa access to third party payers' formularies. Respondent then launched a fraudulent marketing campaign to influence the doctors, who are not ethically allowed

to consider health insurers' costs when prescribing drugs, to prescribe Zyprexa for everything, however baseless the "science" they were fed by respondent. Third party payers paid the tab. Here, the *only* foreseeable financial injury was to third party payers, just as the "one armed bidders" in *BCS Services* were the only parties foreseeably injured by defendants' bid rigging. Third party payers were the *specific target* of respondent's unapproved use marketing efforts, resulting in an exponential increase in Zyprexa prescriptions for useless off-label indications, and causing third party payers' resulting overpayments for the over-prescribed Zyprexa.

Moreover, in *BCS Services*, the Seventh Circuit rejected another argument similar to the one adopted by the Court of Appeals here; that Plaintiffs must bring before the court, one-by-one, the thousands of physicians who prescribed Zyprexa in order to prove that they were influenced to prescribe Zyprexa for unapproved indications as a proximate result of Defendants' fraudulent marketing:

> The plaintiff doesn't have to prove a series of negatives; he doesn't have to "'offer evidence which positively exclude[s] every other possible cause of the accident.'" *Carlson v. Chisholm-Moore Hoist Corp.*, 281 F.2d 766, 770 (2d Cir. 1960) (Friendly, J.), quoting *Rosenberg v. Schwartz*, 183 N.E. 282, 283 (N.Y. 1932). In technical legal terms, the burden of proving an "intervening cause"—something which snaps the "causal chain" (that is operates as a "superceding cause,"

> wiping out defendant's liability, see *Restatement (Second) of Torts* 440 (1965)) that connects the wrongful act to the [plaintiffs] injury—is on the defendant. *Roberts v. Printup*, 595 F.3d 1181, 1189-90 (10th Cir. 2010).

BCS Servs., 2011 WL 1045853, at *6.

The Court of Appeals here made a similar error by "requir[ing] plaintiffs to prove the nonexistence of potential superseding causes, rather than requiring the defendants to present evidence to support their conjectured superseding causes." *Id.* at *7. RICO plaintiffs must only meet the "statistical probabilistic" test to defeat summary judgment.[4]

Reminiscent of the speculation in *BCS Services* that the "one armed bidders" were too slow or that they chose bad seats, both of which defendants there argued as causes of their injuries, respondent here says the third party payers were too slow detecting their fraud, and making formulary decisions because it didn't properly babysit doctors who wrote Zyprexa prescriptions to understand why. Judge Posner, writing for the court, rightly exposed these causation postulates as defendants "throwing sand in the district judge's eyes":

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[4] *See also United States v. McMillan*, 600 F.3d 434, 449 (5th Cir. 2010) ("It is irrelevant for our purposes whether alleged misrepresentations about The Oath's financial condition were made to the state Department of Insurance or directly to the alleged victims of the scheme. The issue is whether the victims' property rights were affected by the misrepresentations.").

> Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct, he has done enough to withstand summary judgment on the ground of absence of causation. *Liriano v. Hobart Corp.*, 170 F.3d 264, 271-72 (2d Cir. 1999); *Kingston v. Chicago* & N.W. Ry., 211 N.W. 913, 915 (Wis. 1927); *Martin v. Herzog*, 126 N.E. 814, 816 (N.Y. 1920) (Cardozo, J.) ("evidence of a collision occurring more than an hour after sundown between a car and an unseen buggy, proceeding without lights, is evidence from which a causal connection may be inferred between the collision and the lack of signals").

BCS Servs., 2011 WL 1045853, at *8. (Emphasis added).

CONCLUSION

Given the size of the pharmaceutical industry, the recent prevalence of marketing misconduct by manufacturers therein, and the centrality of rising healthcare costs to concerns about the Nation's fiscal soundness, the issues raised in the petition dramatically affect the nation's economy. Because of the significance of the issues presented in the petition and the divergence of opinions among the circuits concerning the appropriate RICO causation standards enunciated by this Court in *Bridge* and *Hemi*, the Court should grant the petition for a writ of certiorari.

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