No. 15-1525

IN THE

Supreme Court of the United States

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND, ALLIED SERVICES DIVISION WELFARE FUND,

Petitioners,

v.

SANOFI-AVENTIS U.S. LLP., SANOFI-AVENTIS U.S., INC.

Respondents.

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

BRIEF OF AARP, AARP FOUNDATION, COMMUNITY CATALYST, AND PUBLIC CITIZEN, INC. AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST[1]

Amici are consumer groups that advocate for public health, consumer choice, and the safety, efficacy, and affordability of prescription drugs. Amici submit this brief to describe the effect of pharmaceutical marketing on doctors' medical decisions, and the harms that effect poses for the quality of patient care and the cost of prescription drugs.

AARP is a nonprofit, nonpartisan organization dedicated to fulfilling the needs and representing the interests of people age fifty and older. AARP fights to protect older people's financial security, health, and well-being. AARP's charitable affiliate, AARP Foundation, creates and advances effective solutions that help low-income individuals fifty and older secure the essentials. Among other things, AARP and AARP Foundation advocate to protect consumers from dangerous medical products and rising costs of prescriptions, including through participation as amicus curiae in state and federal courts.

Founded in 1971, Public Citizen, Inc. is a non-profit organization with members and supporters nationwide. Public Citizen has a longstanding interest in public health, including drug safety and regulation by the Food and Drug Administration.

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[1] No counsel for a party authored any part of this brief. Only Amici and their attorneys paid for the filing and submission of this brief. Pursuant to Supreme Court Rule 37.2(a), all parties consented to the filing of this brief.

Among other things, Public Citizen promotes research-based, system-wide changes in health care policy and provides oversight concerning drugs and medical devices. Public Citizen has filed briefs as amicus curiae in numerous cases concerning marketing by pharmaceutical companies and the safety of pharmaceuticals, including *Sorrell v. IMS Health*, 564 U.S. 552 (2011), and *Amarin v. Food and Drug Administration*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

Community Catalyst is a nonpartisan, not-for-profit organization that builds consumer participation in shaping the U.S. health care system to assure quality affordable care for all. Community Catalyst works with state and local partner organizations representing older adults, people with disabilities and chronic illnesses, children and low-income families in over 35 states. Community Catalyst's Center for Consumer Engagement in Health Innovation is working to improve the value that consumers and taxpayers get for their healthcare dollars and has identified excessive prescription drug prices as a critical source of excess health spending in the United States.

SUMMARY OF THE ARGUMENT

In the opinion below, the Second Circuit rejected the opinions from its sister circuits that physicians' prescribing decisions do not break the chain of causation between a drug manufacturer's fraud and a drug purchaser's economic injury under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1964(c). The court did so

because it failed to account for the ways and significant extent to which manufacturers' marketing of pharmaceuticals to doctors corrupts the information process relied upon by doctors to make prescribing decisions. Pharmaceutical companies spend enormous sums of money on direct-to-doctor marketing for one reason: it works. When pharmaceutical marketing is fraudulent or misleading, it interferes with physicians' independent determinations concerning patients' well-being. This influence directly harms patients and their health plans when companies wrongly minimize the health risks of a drug, precisely as alleged in this litigation.

Courts must not ignore the well-established relationship between pharmaceutical marketing and doctors' prescribing decisions. This Court's review of the Second Circuit's unduly restrictive interpretation of RICO causation is essential to protect consumers and health plans from commonplace pharmaceutical marketing fraud.

ARGUMENT

I. PHARMACEUTICAL MANUFACTURERS AGGRESSIVELY MARKET TO DOCTORS TO BOLSTER SALES.

The pharmaceutical industry spends billions of dollars each year marketing prescription drugs to doctors. *See* Pew Charitable Trusts, *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, http://tinyurl.com/mac4o5d (last visited July 20, 2016) (noting that in 2012, "the pharmaceutical

industry spent more than $27 billion on drug promotion"). Indeed, the industry spends significantly more marketing to doctors than it spends marketing to patients: in 2012, "more than $24 billion on marketing to physicians and over $3 billion marketing to consumers." *Id.*

To understand how this marketing has an outsized influence on physicians' prescribing practices, it may be helpful to consider two of the most common types of pharmaceutical marketing. First, pharmaceutical companies market their products by paying for clinical research studies and then touting positive results. While clinical research studies are a critical part of ensuring consumer safety, studies sponsored by a drug company often lack the objectivity and reliability necessary for valid medical research. *See* Editorial, *Sponsorship, Authorship, and Accountability*, 345 New Eng. J. Med. 825 (Sept. 13, 2001). In some instances, pharmaceutical companies have hired ghostwriters to pose as study authors to hide the company's involvement. *See* Joseph S. Ross, et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib*, 299 J. Am. Med. Ass'n 1800, 1800-12 (2008). Often, publication of this type of "research" is marketing designed to generate excitement in the market and, sometimes, to stimulate prescriptions for unapproved uses. *See* Michael A. Steinman et al., *Narrative Review: The Promotion of Gabapentin: An Analysis of Internal*

Industry Documents, 145 Annals Internal Med. 284, 288 (2006).[2]

Second, pharmaceutical companies spend an enormous amount of their marketing budget on "detailing," the practice of pharmaceutical sales representatives visiting the offices of physicians (or otherwise contacting physicians) to promote their company's drugs and/or medical devices. *See IMS Health Inc. v. Ayotte*, 550 F.3d 42, 71 (1st Cir. 2008), *abrogated on other grounds*, *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011); Thomas L. Hafemeister & Sarah P. Bryan, *Beware Those Bearing Gifts: Physicians' Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 Kan. L. Rev. 491, 492-495 (2009). Detailers visit physicians as often as three to five times each week, with each doctor meeting an average of ten representatives a month. *See* Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 Penn. St. L. Rev. 41, 42 (2006) (citing Carl Elliott,

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[2] Nearly 75 percent of all funding for clinical trials in the United States comes from corporate sponsorship. *See* Sameer S. Chopra, *Industry Funding of Clinical Trials: Benefit or Bias?*, 290 J. Am. Med. Ass'n 113 (2003). Physicians are paid, often on a per-patient basis, to participate by enrolling their own patients as subjects. *See* Jammi N. Rao & L.J. Saint Cassia, *Ethics of Undisclosed Payments to Doctors Recruiting Patients in Clinical Trials*, 325 Brit. Med. J. 36, 36 (2002). A 2004 study found that 37 percent of Maryland internists surveyed had participated in pharmaceutical-sponsored clinical trials and lectures to supplement their incomes. *See* Bimal H. Ashar et al., *Prevalence and Determinants of Physician Participation in Conducting Pharmaceutical-Sponsored Clinical Trials and Lectures*, 19 J. Gen. Internal Med. 1140, 1140 (2004).

Better than Well: American Medicine Meets the American Dream 120 (W.W. Norton & Co. 2003)).

Sales visits may include free lunches or dinners at which doctors listen to presentations about the company's products. *See* Hafemeister & Bryan, *supra*, at 496 ("Detailers frequently treat doctors, including hospital residents, to lunches or dinners to discuss the company's products.") (alteration and internal quotation marks omitted); Editorial, *Please Hold the Free Lunches*, N.Y. Times, Aug. 4, 2006, at A16; Jeffrey T. Berger, *Pharmaceutical Industry Influences on Physician Prescribing: Gifts, Quasi-Gifts, and Patient-Directed Gifts*, 3 Am. J. Bioethics 56, 56-57 (2003) (noting that "companies also conduct dinner-lecture programs in which physicians enjoy a meal (typically in a fine restaurant) while listening to a physician lecture on a medical condition that the sponsor's medication is intended to treat.").

The widespread industry practice of delivering marketing messages—designed solely to maximize sales—as if they were objective, reliable, and based on sound scientific studies, is highly sophisticated and effective at influencing doctors' prescribing decisions. *See* Tobias L. Millrood, *When Drug Sales Representatives Go Too Far*, Winter 2007 Am. Ass'n Justice-CLE 521 (2007).

II. PHARMACEUTICAL MARKETING IS FREQUENTLY MISLEADING.

The direct connection between the above marketing and patient health and safety bears emphasis: the marketing is to doctors, but the

patients are the ones who actually purchase and use the drugs. If the marketing conveys inaccurate information, the harm to patients may be significant. Unfortunately, marketing is all-too-often inaccurate or misleading.

A. Unlawful promotion of drugs is commonplace.

Despite Food and Drug Administration ("FDA") regulations prohibiting false or misleading statements about the safety or effectiveness of drugs, *see* 21 C.F.R. § 99.101(a)(4), pharmaceutical companies regularly promote their drugs in misleading and inaccurate ways. Between 2001 and 2005, the FDA sent at least 170 letters to 85 different companies in response to false and misleading pharmaceutical advertising. *See* Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, The State PIRGs 7 (May 2006). In those letters, the FDA highlighted at least 82 times that pharmaceutical companies concealed negative clinical trial results or misreported results. *Id.* at 1. And 37 percent of the misleading messages communicated to doctors involved minimizing or misrepresenting the risks of drugs, precisely as alleged in this litigation. *Id.* at 10.

Similarly, from 2003 to 2007, the FDA sent 42 letters to pharmaceutical companies in response to unlawful off-label promotion, which puts patients at considerable risk of harm. *See* Government Accountability Office, *Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label*

Uses 6 (2008). These enforcement actions under-represent the universe of unlawful marketing; as the FDA acknowledged, "it is very difficult, if not impossible, for FDA's supplementary monitoring and surveillance efforts to identify all off-label promotion that may occur." *Id.* at 17.

Promotion for unapproved uses is common enough that the federal government has brought numerous False Claims Act suits against pharmaceutical companies for unlawful promotion of drugs resulting in prescription drug payments made by government payors. Settlements in these cases exceeded $2 billion from 1991 to 2015. *See* Public Citizen, *Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015 (Chart Book)* 21 (2016).

B. The use of biased clinical studies as marketing tools is highly misleading and corrupts the information process doctors rely upon to make medical decisions.

Industry-funded clinical studies can produce biased results that serve as misleading marketing vehicles rather than providing objective information about a drug's efficacy or safety.

Merck, for example, funded a clinical study of Vioxx that appeared to test the safety of the drug but was actually designed and run by the company's marketing department to promote sales. Kevin P. Hill, et al., *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 Annals of Internal Med. 251, 251-58 (2008). Merck did not disclose to the study participants or the publishing

journal that the study was a marketing exercise. *Id.* Vioxx was pulled from the market when the safety risks were revealed after an estimated 88,000 Americans had heart attacks from taking Vioxx, and 38,000 had died. *See* Snigdha Prakash & Vikki Valentine, *Timeline: The Rise and Fall of Vioxx*, NPR (Nov. 10, 2007).

Similarly, Parke-Davis designed and commissioned research to promote its drug Neurontin and devised a "publication strategy" that included contracts with medical education companies to write articles on specified topics involving its off-label uses in order to influence physician prescribing decisions. *See* C. Seth Landefeld & Michael A. Steinman, *The Neurontin Legacy—Marketing through Misinformation and Manipulation*, 360 New Eng. J. Med. 103, 103-06 (2009). This strategy resulted in tremendous sales of the drug for uses for which it was not effective. *See id.* Parke-Davis's parent company pleaded guilty and paid more than $430 million to resolve criminal charges and civil liabilities. Press Release, *Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion*, U.S. Dep't of Justice, May 13, 2004 ("This illegal and fraudulent promotion scheme corrupted the information process relied upon by doctors in their medical decision making, thereby putting patients at risk [and] depriv[ing health plans] of the informed, impartial judgment of medical professionals . . . on which the program relies to allocate scarce financial resources to provide necessary and appropriate care[.]").

As the primary sponsors of clinical studies, drug companies also have the ability to suppress those with unfavorable results. *See* S. Swaroop Vedula, et al., *Outcome Reporting in Industry-Sponsored Trials of Gabapentin for Off-Label Use*, 361 New Eng. J. Med. 1963, 1963-1971 (2009) (finding that drug companies selectively report the outcomes of clinical trials).

Unsurprisingly, the findings of studies that drug companies choose not to publish are overwhelmingly negative or inconclusive. *See* Erick H. Turner, et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 New Eng. J. Med. 252, 252-260 (2008). For example, Merck reportedly suppressed evidence that Vioxx caused an increased risk of heart attack and attempted to discredit or "neutralize" doctors who were critical of the drug. Stephanie Saul, *Merck used ghostwriters and misrepresented data on Vioxx, article says*, N.Y. Times, Apr. 15, 2008. And analyses of clinical studies of calcium channel blockers found that 51 percent of authors with industry funding reported positive results, and *zero percent* of independent authors reported positive results. Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 J. Am. Med. Ass'n 454, 456 (2003).

III. FRAUDULENT AND MISLEADING PHARMACEUTICAL MARKETING HARMS PATIENTS AND HEALTH PLANS.

False and misleading marketing of medications seriously harms patients when that marketing minimizes a particular drug's risks, as allegedly occurred in this litigation. Fraudulent marketing also drives up costs, further compromising patient safety and putting strain on our health care system, which is already one of the most expensive in the world.

Research consistently demonstrates that aggressive marketing of pharmaceuticals strongly affects doctors' prescribing decisions. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. Am. Med. Ass'n 373 (2002) (surveying 29 studies). As one recent study summarized the research, "a great deal of evidence demonstrates that commercial sources play a substantial role in shaping [doctors'] knowledge and prescribing decisions." Christopher Robertson et al., *Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence*, 40 J. L. Med. & Ethics 452, 459 (2012).

The most common form of marketing—detailing—is particularly effective. Many studies have found a "strong, consistent, specific, and independent association between physicians' behavior and their exposure to detailers." *Id.* (citing studies from 2005, 2000, and 1993) (internal

quotation marks omitted). One study found that "60 [percent] of physicians named commercial sources, such as detailers, as most influential in their first decision to prescribe a drug." *Id.* (citing M. Y. Peay & E. R. Peay, *The Role of Commercial Sources in the Adoption of a New Drug*, 26 Soc. Sci. in Med. 1183, 1183-89 (1988)).

The tremendous impact of pharmaceutical company marketing to physicians is problematic when misleading marketing interferes with "the ability of the physician to make independent determinations concerning the patient's well-being[.]" Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 Cardozo L. Rev. 2241, 2259 (2004); *see also* Lori-Ann Rickard & Amy Fehn, *Recent Developments in Regulation of Pharmaceutical Marketing Practices*, 19 J. Health L. 16, 16 (2006) (finding that "physicians' prescribing practices are . . . affected by interactions with drug companies." Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 J. Am. Med. Ass'n 252, 252 (2003).

Even when the marketing does *not* have a negative impact on patient health, aggressive marketing can still cause serious harm to patients and their health plans. This is so because it results in doctors over-prescribing the newest and most expensive drugs. *See* Paneet Manchanda & Elisabeth Honkal., *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 Yale J. Health Pol'y, L. &

Ethics 785 (2005). Companies promote new brand-name drugs over existing drugs, even where the new product offers no greater health benefits. *See IMS Health*, 550 F.3d at 54; NIHCM Found, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* 3 (2002) (explaining that "[n]ewly-approved medicines are being more heavily marketed to both doctors and consumers," a factor that accounted for 36 percent of the rise in retail prescription spending in 2000 and 24 percent of the rise in spending in 2001).

Indeed, one study found that "[r]equests by physicians that drugs be added to a hospital formulary were strongly and specifically associated with physician's interactions with the companies manufacturing the drugs," even though more than half of the drugs requested provided little or no advantage over drugs already on the formulary. Mary-Margeret Chren & Seth Landefeld, *Physicians' Behavior and their Interactions with Drug Companies*, 271 J. Am. Med. Ass'n 684 (1994).

As a result, patients and health plans pay significantly more due to aggressive pharmaceutical marketing. When marketing is based on fraudulent statements, the doctors' resulting decisions to prescribe the medication do not break the chain of causation between the false statements and the injury to patients and health plans.

CONCLUSION

Against the above backdrop, and for the reasons stated in the petition for a writ of certiorari, the petition should be granted.

July 21, 2016

Respectfully submitted,

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