

APR 25 2011

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 OF DR. BRIAN C. BECKER, DR. SARA
FISHER ELLISON, AND DR. JOSEPH R. MASON
AS AMICI CURIAE IN SUPPORT OF PETITIONERS**

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April 25, 2011

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INTEREST OF *AMICI CURIAE*¹

Amici are professional economists and academics. *Amici* wish to ensure that the Court properly assesses the economic significance that fraudulent marketing has on the prescription drug industry in deciding whether to grant petitioners' writ. *Amici* have no stake in the outcome of this case. They are filing this brief solely as individuals and not on behalf of the institutions with which they are affiliated.

Dr. Brian C. Becker is the founder and President of Precision Economics, LLC. Dr. Becker has produced more than 400 economic expert reports for Fortune 500 corporations, international law firms, the Internal Revenue Service, the Australian Taxation Office, and the Canada Revenue Agency. Focusing on transfer pricing, valuation, damage calculations, and anti-dumping analysis, Dr. Becker has testified in a number of legal venues, including U.S. Tax Court, The Tax Court of Canada, The Australian Administrative Appeals Tribunal, The Federal Court of Australia, The Canadian International Trade Tribunal, Dela-

¹ Pursuant to Supreme Court Rule 37.6, counsel for *amici* represents that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amici* or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amici* notes that, until May 2006, he and James Dugan, one of the counsel for petitioners, practiced law together in the firm Dugan & Browne, PLC. Counsel for *amici* has not personally represented any of the petitioners in connection with this matter and has no financial interest in the outcome of this litigation. Pursuant to Rule 37.2(a), counsel for *amici* represents that all parties were provided notice of *amici's* intention to file this brief at least 10 days before its due date. This brief is filed with the written consent of the parties, reflected in letters on file with the Clerk.

ware Chancery Court, and The U.S. International Trade Commission. In addition to this expert witness experience, Dr. Becker has: (a) published more than two dozen papers/book chapters; and (b) served as a Visiting Professor in the business schools of four universities. Dr. Becker received a B.A. in Applied Mathematics and Economics from the Johns Hopkins University and a M.A. and Ph.D. in Applied Economics from the Wharton School of the University of Pennsylvania.

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Ellison received a B.S. in Mathematics and Statistics from Purdue University in 1987, a diploma of Advanced Study in Mathematical Statistics from Cambridge University in 1988, and a Ph.D. in Economics from the Massachusetts Institute of Technology in 1993.

Dr. Joseph R. Mason is the Moyse/LBA Chair of Banking at the Ourso School of Business at Louisiana State University, and Senior Fellow at the Wharton School. Dr. Mason's academic research focuses primarily on investigating liquidity in thinly traded assets and illiquid market conditions. Current academic research projects analyze default risk, including both immediate and cross-default risk, and default resolution costs in the contexts of asset-backed securities, in systemic and non-systemic environments, as well as the efficacy of bailout and resolution policies through the history of financial markets. His research and economic commentary has received hundreds of national and international press citations in publications such as the *Wall Street Journal*, *New York Times*, *Washington Times*, *The Economist*, *Financial Times*, *Barrons*, *Business Week*, *die Zeit*, *Neue Zürcher Zeitung*, *Financial Times-Germany*, *Los Echos*, *Forbes*, *Fortune*, *Portfolio Magazine*, *Bloomberg Magazine*, *American Banker*, and on press syndicates such as Associated Press, Reuters, Bloomberg, KnightRidder, and MarketWatch-Dow Jones Newswire. Dr. Mason received a B.S. in economics from Arizona State University in 1990 and a Ph.D. from the University of Illinois in 1996.

ARGUMENT

As economists, *amici* believe that this case presents a critical issue for the health-care industry, which represents a substantial and growing share of the National economy. As petitioners explain, the court of appeals' decision in this case has created substantial confusion regarding the legal rules governing lawsuits by private health-benefit providers, or third-party payors, against pharmaceutical manufacturers for the fraudulent marketing of prescription drugs. *Amici* write to elaborate on the economic significance of that confusion for the industry and the broader economy. *Amici* encourage this Court to grant petitioners' writ and remedy the economic confusion the Second Circuit's decision created.

In analyzing this decision, we understand the general facts of this matter to be:

- Respondent fraudulently advertised the drug, Zyprexa, and such actions caused the market price of the product to increase.
- Respondent directed its fraudulent advertising to physicians and patients.
- For most purchases (prescriptions)² of Zyprexa, patients and doctors make little or no payment. *See Figure 3.*
- Unlike typical economic markets where advertising is directed to the product's ultimate payors, private and Governmental third-party payors are responsible for paying the majority of the cost of pharmaceuticals. *See Figure 3.* Thus, the damage to

² We have not been provided specific figures for the purchasers of Zyprexa. Unless otherwise stated, we refer to the overall market summarized in **Figure 3**.

fraudulently inflated prices is on private and Governmental third-party payors.

- In this case, the Governmental third-party payors *were* “made whole” from their loss through a lawsuit directed at respondent.
- In this case, private third-party payors (representing approximately half of the total payment for pharmaceuticals) *were not* made whole by suing respondent, as the Second Circuit ruled that these entities were not the target of the fraudulent advertising.

Given these facts, we believe that third-party payors should be allowed to sue for damages resulting from fraudulent advertising. To the extent that the fraudulent advertising results in increased sales, an increased price, or both, and to the extent that those sales are being paid for by a third party as opposed to the physician or patient, the third party is bearing economic costs and should be allowed to sue to be made whole. In addition, in typical (non-pharmaceutical) economic markets, corporations have a disincentive to market fraudulently in that all of the damaged parties may sue to be made whole, which would potentially eliminate all incremental profits from such acts. If corporations, like respondent, know they can profit from fraudulent marketing with the potential of only a portion of such profit to be paid back to purchasers to be made whole, they are left with an economic incentive to engage in that fraudulent activity.

In this brief, we discuss the unusual structure of the market for prescription pharmaceuticals. It is this unusual structure that gives rise to the situation where three or more parties could be involved in

(i) exposure to advertising, (ii) decision to purchase, (iii) payment, and (iv) consumption of the product. (In a canonical market, the “consumer” typically performs all four of those functions himself.) We also discuss the central role that advertising plays in the market for prescription pharmaceuticals, as demonstrated by the large advertising expenditures made by the manufacturers. The importance of advertising in this market is due in part to an asymmetry of information between the manufacturer and the physician and patient. Advertising also assumes a large role because the unusual structure of the market attenuates the price sensitivity of the parties making the purchase decision. We discuss a number of academic studies that elucidate these points.

I. THE ECONOMIC ORGANIZATION OF THE PHARMACEUTICAL INDUSTRY

A. Prescription Drug Market

The market for prescription pharmaceuticals has always diverged from what economic models treat as the typical, or canonical, market. In particular, there has always been a separation between the decision maker, the physician writing a prescription, and the traditional payor and consumer, the patient taking the drug. In recent years, however, this market has diverged even further from the typical economic market. Increasingly, payment for the drug has also been separated from both the decision to purchase and the consumption of the drug. In 1990, consumer out-of-pocket spending represented approximately 56 percent of total prescription drug expenditures, with private insurance and public funds splitting the remaining share. By 2005, however, consumers were no longer paying the bulk of prescription costs, with their share down to 24 percent and private health

insurance spending up at 48 percent.³ See **Figure 3**. Thus, in the pharmaceutical market, there is now a significant structural separation between consumers and the institutions that pay for their prescriptions.

Typically, economic transactions can be analyzed through the use of standard economic models where there is an exchange of goods and services between two parties, a buyer and a seller. Under such circumstances, the buyer attempts to pay as little as possible and the seller attempts to extract as high a price as possible—with the ultimate price falling somewhere in the middle depending on the positions/bargaining power of the two parties. See **Figure 1**. In this type of market, fraudulent activity of the seller would typically *directly* harm the buyer.

The market for prescription drugs, however, is unlike the typical market for consumer goods. Prescription drugs are seldom exchanged directly between consumer and producer. Rather, multiple entities are involved including patients, physicians, drug companies, and, in some cases, third-party payors. See **Figure 2**.

The presence of these various actors in a single transaction complicates the classic economic model of supply and demand. Under the current system, the patient neither pays for nor chooses the good. Instead, physicians decide what drugs to prescribe and third-party payors purchase the prescriptions on behalf of patients. This complex set of relationships separates the patient (consumer) from the drug company (producer). In these situations, fraudulent activity by the seller that artificially inflates price

³ See Janet Lundy, *Prescription Drug Trends*, The Henry J. Kaiser Family Foundation 2 (2010).

will directly harm not the consumer, but rather the third-party payor.⁴ See **Figure 2**.

B. Prescription Drug Advertising

The pharmaceutical industry is unusual in other ways as well. Unlike many other markets, it is characterized by the central and important role that advertising plays. There are a number of factors that influence the nature of pharmaceutical advertising and contribute to its importance. First is the structure of the market discussed above. In such a situation, we would expect pharmaceutical companies to engage in advertising directed primarily at the decision maker, the physician, but also, perhaps, to the patient, who could influence the physician's decision. We would also expect the advertising to focus on drug characteristics, not prices, because the targets of their advertising are typically not bearing the cost of the drug.

Second is the asymmetric information that characterizes the pharmaceutical market. In particular, pharmaceutical companies, which run clinical trials and have access to a large amount of information on the safety and efficacy of their drugs, would know much more about a product's characteristics than patients, or even relatively well-informed physicians, would.

Finally, the content of pharmaceutical advertising is subject to strict regulations by the Food and Drug

⁴ The market for insurance premiums operates under an assumption of truthful information/marketing. Third-party payors would (attempt to) charge higher premiums after discovering fraudulent marketing. However, they would suffer losses during the time before such fraudulent activity is discovered. In that sense, insurance companies may not retroactively increase prior insurance premiums.

Administration (“FDA”). The strict regulations, coupled with the asymmetry of information, lead to an unusual reliance by physicians and patients on advertising by the manufacturer.

Since pharmaceutical companies know far more about the efficacy of the drugs that they create than consumers and even the physicians who act as consumers’ agents, physicians and patients must rely, therefore, on the information contained in the advertising materials to make as well-informed a decision as possible. FDA regulations on the content of pharmaceutical advertising provide assurances of the scientific accuracy of advertised claims. According to those regulations, pharmaceutical sales representatives must communicate complete information concerning benefits and side-effects, and cannot distort facts about their own products or competitors’ products.⁵ For example, information regarding efficacy must be presented with the associated risks, to prevent a misleading profile of the drug. The FDA also requires that drug marketers only use information that is supported by sound evidence from clinical studies.⁶ Furthermore, it is prohibited for companies to market drugs for unapproved uses. Indeed, the FDA mandates “prescription drug labeling,” which

⁵ See, U.S. Food and Drug Administration, *Truthful Prescription Drug Advertising and Promotion (Bad Ad Program)* (Apr. 15, 2011), available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm>.

⁶ See *id.*; Federal Food, Drug, and Cosmetic Act, § 502(n), 21 U.S.C. § 352(n); U.S. Food and Drug Administration, *Background on Drug Advertising* (Apr. 15, 2011), available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm>.

requires full disclosure about what a prescription medicine is supposed to do, who should and should not take it, and how to use it.⁷ Asymmetric information coupled with these strict regulations ensures that pharmaceutical advertising is an important source of information for physicians and patients.

Although all of these factors affect the importance of advertising in this market and the likelihood that advertising will result in higher profits for the manufacturers, we take the large advertising budgets of the manufacturers as *de facto* evidence that advertising increases sales, allows the manufacturers to increase price, or both. Otherwise, they would not engage in these expenditures.

This is not surprising given that the safety and efficacy of a drug, as well as the conditions for which it is approved, should determine the price a company can charge and the volume it sells, and these are characteristics conveyed by advertising. Companies, therefore, face strong incentives to design their advertising to highlight the drug's therapeutic advantages and suggest wide applicability.

⁷ See U.S. Food and Drug Administration, *An FDA Guide to Drug Safety Terms* (Apr. 15, 2011), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107970.htm>.

II. WITHOUT THIS COURT'S INTERVENTION, THE COURT OF APPEALS' DECISION WILL PERVERSELY INCENTIVIZE PHARMACEUTICAL COMPANIES TO USE FRAUDULENT MARKETING TO INCREASE DRUG COSTS

In the 1960s, Nobel Laureate George Stigler created a revolution in economic thought by analyzing information as a scarce commodity. In analyzing information as an economic good in and of itself, Professor Stigler recognized that, like any other economic commodity, financial and institutional incentives affect the information available to consumers. *See* George J. Stigler, *The Economics of Information*, 69 J. Pol. Econ. 213-225 (1961).

Economists evaluate the consequences of marketing in terms of the economics of information. When advertising reduces consumers' costs of acquiring information, it increases economic efficiency by facilitating mutually beneficial transactions between sellers and buyers. However, economists also recognize that, when sellers suppress information that would affect buyers' valuations of the sellers' products, advertising can be used as a tool to mislead unaware consumers. Under typical conditions, misleading advertising misallocates scarce resources and therefore reduces consumer surplus—consumers end up with products they do not value, money is poured into economically destructive marketing schemes, and prices will exceed the efficient level. *See* Darrell L. Hueth, Richard E. Just & Andrew Schmitz, *The Welfare Economics of Public Policy: A Practical Approach to Project and Policy Evaluation* 443 (Edward Elgar Publishing Limited 2004).

On the above point, Nobel Laureate Professor Joseph Stiglitz and Professor Steven Salop demonstrated through what they termed the “Bargains and Ripoffs” model that, in the context of asymmetric information, markets may become characterized by recurring, economically inefficient price increases. See Joseph Stiglitz & Steven Salop, *Bargains and Ripoffs: A Model of Monopolistically Competitive Price Dispersion*, 44 Rev. Econ. Studies 493 (1977). A similar result was demonstrated in a 1979 article in the *Quarterly Journal of Economics* by Professors Dennis Smallwood and John Conlisk. The authors showed how consumer uncertainty regarding product quality would lead to market outcomes where “consumers pay considerably for being uninformed.” Dennis E. Smallwood & John Conlisk, *Product Quality In Markets Where Consumers Are Imperfectly Informed*, 93 Q.J. Econ. 18 (1979).

The pharmaceutical industry is certainly vulnerable to these price distortions resulting from information asymmetry, but, in the context of the prescription drug market, it is often the third-party payors that end up bearing the cost. Physicians are insulated from the process of paying for the medications they prescribe. Additionally, patients—who typically follow the guidance of their physicians—may pay little or nothing for their prescriptions. With such limited “stakes” in the *pricing* of pharmaceuticals, consumers (patients) and doctors would suffer—at most—little damage from artificial price increases due to fraudulent activity (even if patients would suffer from ineffective pharmaceuticals).

Third-party payors represent a very different position in the pharmaceutical market than patients and physicians. First, they often have little influence in

choosing prescription drugs for usage by their policyholders. Second, they typically *pay* for the pharmaceuticals that are purchased. As such, they bear the risk of additional/higher costs if fraudulent marketing causes a drug's volume or unit price to rise artificially. Third, they target their own revenue stream (insurance premiums) based upon factual data and projections that assume non-fraudulent marketing. Given the unusual separation between prescription, usage, and payment in the pharmaceutical industry and the pervasive asymmetric information in the industry, without adequate legal safeguards pharmaceutical companies will have strong incentive to use fraudulent marketing to take advantage of consumers and third-party payors.

Empirical medical and economic literature confirms that there are strong incentives for drug companies to use fraudulent marketing to the detriment of consumers and third-party payors. A study by Doctors Mary-Margaret Chren and Seth Landefeld in the *Journal of the American Medical Society* showed that drug companies' marketing overtures had strong effects on physician behavior. Specifically, the authors aver that their results demonstrate 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." Mary-Margaret Chren & Seth Landefeld, *Physicians' Behavior and their Interactions with Drug Companies*, 271 *JAMA* 684 (1994). Furthermore, the authors found that more than half of the drugs requested provided "little or no advantage" over drugs already on the formulary. *Id.* Of course, this result is not surprising considering the enormous amount of money that pharmaceutical

companies spend on advertising and marketing. There can be little doubt that marketing is an extremely powerful tool that pharmaceutical companies can use to increase demand for their products.⁸

Not only can pharmaceutical companies use marketing as a tool to strengthen demand, but the academic literature also indicates that such marketing allows *drug companies to raise their prices*. In a study published in the *Journal of Law and Economics*, Professor John Rizzo of Stony Brook University found that “product promotion inhibits price competition in the pharmaceutical industry, lowering price elasticities and leading to higher equilibrium prices.” John Rizzo, *Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Anti-hypertensive Drugs*, 42 *J.L. Econ.* 89, 112-113 (1999). More recently, two economists affiliated with the National Bureau of Economic Research, Dhaval Dave and Henry Saffer, studied the effects of direct-to-consumer advertising of prescription drugs and found that direct-to-consumer advertising is associated with both increased sales and higher prices. They estimate that as much as 19 percent of the recent increases in drug expenditures can be attributed to the growth of direct-to-consumer advertising. See Dhaval Dave & Henry Saffer, *The Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand*, NBER Working Paper No. 15969 (2010).

In addition to fraudulent marketing being a device for raising pharmaceutical prices by lowering elasticity of demand, fraudulent marketing may be used by

⁸ This particular example of marketing is not fraudulent, per se. However, it further demonstrates how pharmaceutical companies can exercise power through marketing.

pharmaceutical companies, as it was in the case of Zyprexa, to justify a premium (monopoly) price for a drug where the drug's relative efficacy would not demand such a premium to competing treatments. While such instances may not increase the overall (unit) purchases of pharmaceuticals, it will increase the total cost of those treatments. It is well-recognized in the economic literature that drugs that represent significant therapeutic advances over existing treatments command premium prices. For instance, in an article summarizing the state of economic knowledge about drug prices and demand, Professor Ernst Berndt of the Massachusetts Institute of Technology wrote, "For the United States, which accounts for not quite half of global branded prescription drug sales, empirical evidence is consistent with the notion that manufacturers price based primarily on marginal value," the perception of which is increased through advertising. Ernst R. Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16 J. Econ. Persp. 45, 59 (2002). In a statistical analysis published in the Review of Economics and Statistics, Professor William Comanor and Dr. Z. John Lu quantified the value to drug companies of introducing a drug with significant therapeutic advantages over existing treatments. The authors explained, "This paper provides empirical evidence on the leading factors affecting the prices of new pharmaceuticals, both at introduction and after 4, 6, and 8 years. Most important is the extent of the therapeutic advance embodied in a new product. For drugs which represent important therapeutic gains, launch prices can be two or three times those of existing drugs used for the same purposes." William S. Comanor & Z. John Lu, *Strategic Pricing of New Pharmaceuticals*, 80 Rev. Econ. Stat.

108 (1998). Thus, the potential gains from fraudulent marketing create strong incentives for corporate malfeasance absent strong legal institutions for discouraging such behavior.

In the current matter, the specific quantification of the artificial fraudulent increases to the price of Zyprexa proved to represent more than a trivial amount. The U.S. government—handling less than 30 percent of the prescription drug market—recovered damages of approximately \$800 million in a total settlement of \$1.4 billion.⁹ With third-party payors representing a larger share of the prescription drug market (see **Figure 3**), the damage inflicted on their payments would also be expected to be significant.

Allowing third-party payors to sue drug companies for fraudulent marketing not only helps to compensate them for the overcharges suffered as a result of the fraud, but is an essential tool for discouraging drug companies from engaging in fraudulent marketing. See William Landes & Richard Posner, *A Positive Economic Analysis of Products Liability*, 14 J. Legal Stud. 535 (1985); William Landes & Richard Posner, *Tort Law as a Regulatory Regime for Catastrophic Personal Injuries*, 13 J. Legal Stud. 417 (1984); Steven Shavell, *A Model of the Optimal Use of Liability and Safety Regulation*, 15 RAND J. Econ. 271 (1984). Furthermore, by discouraging fraudulent marketing, the threat of litigation from third-party

⁹ See U.S. Dep't of Justice, Press Release, *Eli Lilly and Company Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa* (Apr. 18, 2011), available at <http://www.justice.gov/opa/pr/2009/January/09-civ-038.html>; Janet Lundy, *Prescription Drug Trends*, The Henry J. Kaiser Family Foundation 2 (2010).

payors will likely increase the pharmaceutical industry's investment in socially beneficial advertising that provides accurate information to consumers and doctors.

III. SIZE OF ECONOMIC IMPLICATIONS

The discussion above revealed how fraudulent activity for a single pharmaceutical caused price distortions of approximately \$800 million over less than 30 percent of that market. Zyprexa, however, represents only a small part of the prescription drug industry, which reported sales of over \$1 trillion from 2001 to 2005. See **Figure 4**. Thus, the potential losses to the U.S. Government/third-party payors—and gains to the pharmaceutical companies—could easily reach tens of billions of dollars annually.

IV. SUMMARY

The structure of the pharmaceutical industry uniquely features the party paying for product as being different from the party targeted by marketing (fraudulent or otherwise). In this way, price increases resulting from fraudulent marketing typically do not harm physicians or patients, but rather third-party payors. While *Governmental* third-party payors have been allowed to recover hundreds of millions of dollars in damages resulting from fraudulent advertising, the Second Circuit has prevented private third-party payors from demanding such redress. Without such accountability, pharmaceutical companies will have a significant economic incentive to pursue fraudulent marketing. A reversal of the Second Circuit's decision would restore an equilibrium to this market in which fraudulent marketing would run the risk of liability to both Governmental and private third-party payors.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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April 25, 2011