09-0222-cv

United States Court of Appeals

for the

Second Circuit

UFCW LOCAL 1776 and participating employers health and welfare fund, ERIC TAYAG, and MID-WEST NATIONAL LIFE INSURANCE COMPANY OF TENNESSEE, on behalf of themselves and others similarly situated, LOCAL 28 SHEET METAL WORKERS, on behalf of themselves and others similarly situated, SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated,

Plaintiffs-Appellees,

– v. –

ELI LILLY AND COMPANY,

Defendant-Appellant,

TEXAS DEPARTMENT OF STATE HEALTH SERVICES,

Defendant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF FOR *AMICI CURIAE* AARP AND PRESCRIPTION ACCESS LITIGATION IN SUPPORT OF PLAINTIFFS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1, counsel for Amici AARP and Prescription Access Litigation certify that:

1. Amicus curiae AARP is a non-profit corporation that does not have any parent corporations and any publicly held corporations that own 10% or more of its stock.

2. Amicus curiae PAL is a non-profit corporation, wholly owned by the non-profit corporation Community Catalyst, Inc., and no publicly held corporations own more than 10% of its stock.

Dated: June 30, 2009

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CHRISTIAN SIEBOTT

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CONSENT TO FILING

The parties consent to the filing of this brief.

STATEMENT OF INTEREST

AARP is a nonpartisan, nonprofit membership organization of nearly forty million persons, age fifty or older, dedicated to addressing the needs and interests of older people. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. AARP therefore has a strong interest in this case since the challenged practices thwarted the use of generic pharmaceuticals in the marketplace, thereby reducing access to affordable prescription drug treatments. Affordable prescription medication is particularly important to the older population, which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010, at 2 (July 2000), http://familiesusa.org/assets/pdfs/drugod852b.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. To that end, AARP has worked at the state and national levels for laws and policies that will bring more competition to the marketplace.

See e.g., AARP, *Rx Watchdog Report*, Apr. 2009, Vol. 6, Issue 3, *available at* http://assets.aarp.org/www.aarp.org_/cs/health/rx_watchdog_apr09.pdf.

Prescription Access Litigation LLC ("PAL") is a project of Community Catalyst, Inc., a nonprofit, nonpartisan organization that builds consumer participation in the shaping of the U.S. health system to ensure quality, affordable health care for all. PAL has built a nationwide coalition of over 130 organizations in thirty-five states and the District of Columbia, with a combined membership of over thirteen million people. PAL works to end illegal prescription drug price inflation by pharmaceutical manufacturers and others by facilitating the participation of its coalition's consumers, senior, advocacy and union organizations in class action litigation targeting these practices.

SUMMARY OF ARGUMENT

Pharmaceutical companies spend billions of dollars each year to persuade doctors to prescribe their products. Their marketing efforts are comprehensive and effective, but unfortunately too often lead to pernicious consequences. Studies show that marketing to doctors leads to the over-prescription of newer, more expensive name-brand drugs, and to the under-prescription of equally effective alternatives. Likewise, doctors who are subject to illegal off-label marketing are more likely to prescribe drugs for off-label uses, even when the evidence of efficacy is lacking. When the information the doctors receive from pharmaceutical

companies is incomplete or inaccurate, the consequences are both expensive and injurious.

The FDA is ill-equipped to monitor the marketing and use of prescription drugs after entry to the marketplace. As the Supreme Court has noted, "[t]he 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). Private law suits like this thus serve as an essential supplement to government monitoring and regulatory action. It is respectfully submitted that this Court should affirm the district court's decision and permit this case to proceed as a class action.

ARGUMENT

I. Deceptive Pharmaceutical Marketing Harms Consumers, Leads to High Costs and Decreases Access to Treatment

A. Pharmaceutical Marketing is Aggressive

Physicians are inundated with messages about drugs. The pharmaceutical industry spends billions of dollars each year marketing their products to doctors. Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 Cardozo L. Rev. 2241, 2257 (2004) ("Calabro") ("Annually, the pharmaceutical industry spends $12 billion promoting and marketing their products to physicians through gifting, travel reimbursements

and meal expenses, with approximately $10,000 being spent on each individual physician." (citing H.R. 2641, 107th Cong. (2001))); Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 Penn St. L. Rev. 41, 42 (2005) ("Greene") ("[T]he $2.4 billion spent on consumer advertising pales in comparison to the more than $8 billion spent each year on marketing to physicians."); Tobias L. Millrood, *When Drug Sales Representatives Go Too Far*, Winter 2007 Am. Ass'n Justice-CLE 521 (2007) ("Millrood") ("By 2000, pharmaceutical companies spent $15.7 billion promoting their products, with the largest share (84%) directed toward medical professionals through commercial detailing, drug samples, and journal advertisements." (citing M.B. Rosenthal *et al.*, *Promotion of Prescription Drugs to Consumers*, 346 New Eng. J. Med. 498 (2002))). Most of this money is spent on "detailing" -- direct contact with physicians, including office visits, to promote drugs or medical devices. Detailers provide physicians with sponsorships to educational symposia, pamphlets, drug samples, and "freebies" like textbooks and stethoscopes, notepads, pens, rulers, golf balls, and other items engraved with the logo of the drug company and the product's name. Susan Heilbronner Fisher, Note, *The Economic Wisdom of Regulating Pharmaceutical "Freebies,"* 1991 Duke L.J. 206, 210 (1991) ("Fisher"). Physicians meet with detailers as often as three to five times each week, Fisher at 210, with an average of ten representatives a month visiting each

doctor, Greene at 42 (citing Carl Elliott, *Better than Well: American Medicine Meets the American Dream*, at 120 (W.W. Norton & Co. 2003)).[1]

Pharmaceutical companies also hire physicians to join detailers on office visits, to give lectures to groups of physicians, or to participate in clinical research studies. Some physicians who have been engaged as arms of the pharmaceutical industry have described their experiences. James Stein, a cardiologist, has recently spoken publicly about his decade of experience as a "thought leader" for drug and medical device companies. John Fauber, *Physician Found Money, Acclaim Seductive*, JSOnline, Apr. 29, 2009, *available at* http://www.jsonline.com/features/health/43933562.html. In 1994, Stein was flown first class from Madison to Dallas, where a limousine waited to drive him to speak at a drug company-funded lecture to a group of doctors. *Id.* As he left the stage, he was handed a $500 check and told, "[t]here's more where that came from, son." *Id.* Stein said that in subsequent years he was flattered, as companies paid him thousands of dollars per lecture and told him over and over again that he was a

[1] Pharmaceutical companies are not only concerned with publicizing their own products, they also exert pressure on doctors to switch patients' prescriptions. Peter Keating, *Why You May be Getting the Wrong Medicine: A Money Investigation Reveals How Big Drug Companies Are Pressuring Doctors, Pharmacists and Insurers to Push Prescriptions that Benefit Company Bottom Lines--But May Also Harm Your Health*, Money, June 1, 1997, at 142. "[D]octors are regularly bombarded with letters, calls and faxes -- many including offers of cash payments -- urging them to stop prescribing certain medications in favor of others." *Id.*

future thought leader. *Id.* After more than ten years of giving talks to his peers, Stein says that he has "learned that human beings, physicians included, are incapable of recognizing bias in themselves . . . especially when money is involved." *Id.*

Another physician, Douglas Melnick, worked in the pharmaceutical industry as a physician in medical affairs, supporting marketing for over five years. In a recent article, he and a co-author draw on personal experience, contacts and information from public fora to talk about the ways in which drug companies get around laws against off-label promotion. Douglas Melnick, Adriane Fush-Berman, *Off-Label Promotion, On-Target Sales*, 5 PLoS Med. 1432 (Oct. 2008). Doctors hired as "thought leaders" or "key opinion leaders" are considered crucial for the promotion of off-label uses. *Id.* at 1433. Since they are not company employees, doctors can sign off on industry-produced reviews and commentaries; write case studies; comb patient medical records for cases that promote off-label use; participate in drug-industry sponsored education programs by presenting talks prepared by the sponsoring company. *Id.* at 1433-34. Melnick and his co-author warn that "[p]harmaceutical marketing has distorted the discourse on off-label uses and encouraged the unmonitored, potentially dangerous use of drugs by patients for whom risks and benefits are unknown." *Id.* at 1434.

Pharmaceutical companies also pay for clinical research. Nearly seventy-five percent of all funding for clinical trials in the United States comes from corporate sponsors. Sameer S. Chopra, *Industry Funding of Clinical Trials: Benefit or Bias?*, 290 JAMA 113, 113 (2003) (citing Thomas Bodenheimer, *Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry*, 342 New Eng. J. Med. 1539, 1539 (2000)). "Increasingly, clinicians are invited . . . to participate in clinical trials of newly developed drugs, . . . often [by] enrolling their own patients as subjects." Susan L. Coyle, *Physician-Industry Relations. Part 1: Individual Physicians*, 136 Annals Internal Med. 396, 399 (2002). "Doctors are often paid to recruit patients to [these] clinical trials," usually on a per-patient basis. Jammi N. Rao & L.J. Sant Cassia, *Ethics of Undisclosed Payments to Doctors Recruiting Patients in Clinical Trials*, 325 Brit. Med. J. 36, 36 (2002); Center Watch: Clinical Trials Listing Service, *Background Information on Clinical Research*, http://www.centerwatch.com/patient/backgrnd.html #Section3 (last visited Nov. 1, 2008). A November 2004 study published in the Journal of General Internal Medicine reported that thirty-seven percent of Maryland internists surveyed had participated in pharmaceutical-sponsored clinical trials and lectures to supplement their incomes. 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).[2]

[2] A 2003 article appearing in the Journal of the American Medical Association assessed the impact of funding sources on research results. The researchers concluded that the sponsorship of a study was very closely associated with the outcome reported, even in the case of random controlled trials: "Strong and consistent evidence shows that industry-sponsored research tends to draw pro-industry conclusions . . . . [W]e found that industry-sponsored studies were significantly more likely to reach conclusions that were favorable to the sponsor than were nonindustry studies." Justin E. Bekelman *et al.*, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 463 (2003). The authors performed a meta-analysis of thirty-seven published quantitative studies that compared the source of funding with the outcomes of 1140 biomedical studies, many of which were drug studies. *Id.* at 454, 456. The study examined the aggregation of data over several studies of single drugs or other medical interventions. *Id.*

The pattern of "pro-industry conclusions," as the authors termed the phenomenon, was sometimes pronounced. *Id.* For example, studies of the results of articles on calcium channel blockers reported that fifty-one percent of authors with industry funding reported positive results in trials of the drugs, while zero percent of authors of studies that were not sponsored by interested firms reported positive results. *Id.* at 456. Other studies showed less dramatic differences, but a difference of approximately twenty percent was common when comparing the rate of positive and negative outcomes over the aggregated studies of particular drugs or other interventions. *Id.* at 458; *see also* Mohit Bhandari *et al.*, *Association Between Industry Funding and Statistically Significant Pro-Industry Findings in Medical and Surgical Randomized Trials*, 170 Can. Med. Ass'n J. 477, 477 (2004); James F. Fries & Eswar Krishnan, *Equipoise, Design Bias, and Randomized Controlled Trials: The Elusive Ethics of New Drug Development*, 6 Arthritis Res. & Therapy 3, R250 (2004), *available at* http://www.pubmedcentral.nih.gov; J. Lexchin *et al.*, *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 Brit. Med. J. 1167, 1167 (2003), *available at* http://www.pubmedcentral.nih.gov.

Pharmaceutical companies also regularly sponsor continuing medical education ("CME") programs (which, like CLE for lawyers, physicians must attend to maintain their licensure). Arnold S. Relman, *Separating Continuing Medical Education from Pharmaceutical Marketing*, 285 JAMA 2009, 2009-12 (2001) ("Relman"). The industry provides a substantial proportion of the several billion dollars spent on CME annually, influencing nearly every aspect of CME programming. *Id*. at 2009; *see also* Marshall B. Kapp, *Drug Companies, Dollars, and the Shaping of American Medical Practice*, 29 S. Ill. U. L.J. 237, 247 (2005) ("Kapp") ("CME financial sponsorship may substantially influence the subsequent prescribing behavior of physician attendees; in other words, this form of promoting its product 'works' for drug companies."). This may include organizing and advertising the event; preparing teaching slides and curriculum materials; compiling lists of possible speakers, who may also be recipients of funding for clinical research supplied by the pharmaceutical company; subsidizing the attendance of practitioners, medical students, residents, and fellows; and providing free meals and other amenities for attendees at these programs. Relman at 2009. "At, or adjacent to, virtually all educational sessions subsidized by industry, [pharmaceutical] sales representatives are allowed to display and promote the company's products, particularly [those] related to the [focus] of the program." *Id.* Educational materials are prepared by the pharmaceutical company, and physicians

are paid honoraria to lecture at CME events or other speaking engagements with an implicit understanding that the physician will mention the sponsoring company's product. Fisher at 211-12.

And finally, pharmaceutical companies sometimes provide physicians "payment for attending meetings of specious advisory boards at which little advising by physicians, and a great deal of marketing to physicians, occurs." Jeffrey T. Berger, *Pharmaceutical Industry Influences on Physician Prescribing: Gifts, Quasi-Gifts, and Patient-Directed Gifts*, 3 Am. J. Bioethics 56, 56 (Summer 2003). "Physicians might be further enticed to attend [these meetings] with the promise of a gift check to be used for 'professional or practice-related' activities." *Id.*

B. Pharmaceutical Marketing is Too Often Inaccurate

Physician's need up-to-date information about the newest drugs on the market, and the pharmaceutical industry is essential to that end. Paul H. Rubin, *Pharmaceutical Marketing: Medical and Industry Biases*, 13 J. Pharma. Fin., Econ. & Pol'y 65, 65 (2004). It is both expensive to communicate this information to physicians, and expensive (in terms of lost time) for physicians to absorb the information. *Id.* Pharmaceutical companies can bear the costs of transmitting this information and play a pivotal role in this dissemination. *Id.* Furthermore, pharmaceutical manufacturers must warn physicians of the side effects and other

risks of their prescription drugs. *Restatement (Third) of Torts*: Prod. Liab. § 6 (1998); Ozlem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?*, 81 U. Det. Mercy L. Rev. 267, 286 (2004). Detailing, lectures, and other marketing efforts often provide an opportunity for pharmaceutical companies to do this.

All too often, however, drug marketers provide false or misleading information about their products to doctors, and as a result patients are placed at risk. Between 2001 and 2005, for instance, the FDA wrote at least 170 letters to eighty-five different companies for false and misleading advertising related to pharmaceuticals. Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients At Risk* (The State PIRGS May 2006) ("USPIRG Study"), *available at* https://www.uspirg.org/uploads/De/fW/DefWTYr4wkaB3QbShc6yKw/TurningMedintoSnakeOil.pdf at 7. Of those 170 cases, about sixty-two were targeted at physicians and in one third, the misinformation understated or misrepresented the risks of medications. *Id.* In nearly half of the cases, the pharmaceutical companies concealed negative clinical trial results or misreported results. *Id.* Another study published in the Journal of the American Medical Association ("AMA") found that eleven percent of all favorable statements made by pharmaceutical representatives

were inaccurate. *See* Michael G. Ziegler, Pauline Lew & Brian C. Singer, *The Accuracy of Drug Information from Pharmaceutical Sales Representatives*, 273 JAMA 1296, 1297 (1995).

C. Doctors' Medical Decisions Are Impacted by Marketing

Though necessary to the dissemination of vital information to doctors, the negative impacts of pharmaceutical marketing are significant. The AMA has stated that pharmaceutical marketing can hurt the physician-patient relationship because "[w]hen physicians accept personal inducements, others [including patients] may perceive that the physicians will not fulfill their professional obligations appropriately and fairly." Beverley D. Rowley *et al.*, *Professionalism and Gifts to Physicians from Industry*, *What You Should Know About Gifts to Physicians from Industry*, Am. Med. Ass'n (2003), at 36, *available at* http://www.ama-assn.org/ama1/pub/upload/mm/437/ama_m3_pg.pdf.

Studies have strongly demonstrated that physicians' prescription writing behavior is directly influenced by the types of interactions they have with pharmaceutical companies. *E.g.*, Mary-Margaret Chren & C. Seth Landefeld, *Physicians' Behavior and Their Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary*, 271 JAMA 684 (1994). Simply put, doctors are more likely to prescribe drugs that have been marketed to them. Calabro at 2257; Fusun F. Gonul *et al.*, *Promotion of*

Prescription Drugs and Its Impact on Physicians' Choice Behavior, 65 J. Marketing 79 (2001); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 J. Am. Med. Ass'n 373 (2000) ("Wazana") (surveying twenty-nine studies of the relationship between physicians and the pharmaceutical industry and finding that there was a marked relationship between interactions with industry and prescribing practices); M.A. Morgan, *et al.*, *Interactions of Doctors with the Pharmaceutical Industry*, 32 J. Med. Ethics 559 (2006) (finding that doctors acknowledged a relationship between free drug samples and prescribing practices); Gregory Kruse, *Pharmaceutical Detailing and Medication Choice: A Micro-Level Analysis of Statins*, June 18, 2007, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=994961.

Multiple studies have found that pharmaceutical marketing, including the distribution of "freebies"-- even if the financial value of the gifts is negligible -- taints physicians' medical judgment. *See, e.g.*, Calabro at 2259 ("[Marketing undermines] the ability of the physician to make independent determinations concerning the patient's well-being and to function as a learned intermediary."); Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252, 252 (2003); Fisher at 213 (Freebies "taint the prescribing process and prevent doctors from making objective assessments of the optimal prescribing choices for their patients."); Kapp at 249-50

("[T]here is substantial social science evidence that the subtle, frequently unconscious influence of drug company gifts on physician prescribing behavior may be quite real and powerful . . . . [I]t appears that the size of the gift does not determine the response; in other words, even gifts of negligible financial value can influence the behavior of the recipient in ways that the recipient does not realize."); Jerome P. Kassirer, *Financial Indigestion*, 284 JAMA 2156, 2156 (2000); Dana Katz *et al.*, *All Gifts Large and Small: Toward and Understanding of the Ethics of Pharmaceutical Industry Gift Giving*, 3 Am. J. Bioethics 39, 39 (Summer 2001); Lori-Ann Rickard & Amy Fehn, *Recent Developments in Regulation of Pharmaceutical Marketing Practices*, J. Health L., Dec. 2006, at 16 ("[P]hysician's prescribing practices are, in fact, affected by interactions with drug companies."); Wazana at 373. For example, a study by the Cleveland Clinic Foundation "examined the impact [of] . . . all-expenses-paid trips to popular Sunbelt vacation sites to attend symposia sponsored by a pharmaceutical company" on the prescribing patterns of physicians. James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch*, 102 Chest J. 270, 270 (1992). The study tracked the pharmacies' "usage reports for two drugs before and after the symposia." *Id.* Despite the physicians asserting that the symposia would not alter their prescribing patterns, a significant increase in the prescribing pattern of both

drugs occurred following the symposia, which was "significantly different from the national usage patterns of the two drugs by hospitals [and other] major medical centers over the same period of time." *Id.* Pharmaceutical marketing has also impacted the total number of prescriptions written. Instead of opting for "less risky or expensive approaches" to a medical condition, "such as changes in diet and exercise," often physicians, influenced by marketing, opt for medication. Rebecca Dresser, *Pharmaceutical Company Gifts: From Voluntary Standards to Legal Demands*, Hastings Ctr. Rep., May-June 2006, at 5.

Ultimately, aggressive marketing to physicians leads to over-prescribing the newest and most expensive drugs, often before potentially harmful side effects are known. Puneet Manchanda *et al.*, *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); NIHCM Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, at 3, http://www.nihcm.org/~nihcmor/pdf/spending2001.pdf. Often, the new, more expensive drugs are no better, and sometimes worse, than alternatives. The Prescription Project, *The Constitutional Battle Over State Regulation of Data Mining* (Aug. 2007), at 14 http://www.prescriptionproject.org/tools/solutions_resources/files/0005.pdf . Even when side effects are known, they may be concealed: A recent study showed that

thirty-seven percent of the misleading messages communicated to doctors involved minimizing or misrepresenting drugs' risks. USPIRG Study at 10.

D. Marketing Increases the Cost of Medical Care

Not only has pharmaceutical marketing impaired quality of medical care, it also increases the cost of care. For example, marketing promotes the use of brand-name medications over generic drugs, even though the latter are considerably cheaper. Jennifer S. Haas *et al.*, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey*, 1997-2000, 142 Annals Internal Med. 891, 891 (2005) (finding that sixty-one percent of multisource drugs were dispensed as generic); Anthony D. Bower & Gary L. Burkett, *Family Physicians and Generic Drugs: A Study of Recognition, Information Sources, Prescribing Attitudes, and Practices*, 24 J. Fam. Prac. 612, 614-15 (1987). Over seventy percent of prescriptions are written for drugs for which both generic and brand-name versions are available, but fewer than thirty percent of prescriptions are written for the generic version. Judith K. Hellerstein, *The Importance of the Physician in the Generic Versus Trade-Name Prescription Decision*, 29 Rand J. Econ. 108, 108 (1998) (citing Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J. L. & Econ. 331 (1992)). Generic drug manufacturers spend considerably less on marketing than their brand-name counterparts;

therefore, doctors are probably "less likely to think of generic alternatives" when writing prescriptions. Benjamin P. Falit, *Curbing Industry Sponsors' Incentive to Design Post-Approval Trials that are Suboptimal for Informing Prescribers but More Likely than Optimal Designs to Yield Favorable Results*, 37 Seton Hall L. Rev. 969, 1001 (2007).

In a relatively recent analysis of Medicaid prescription drug spending, two researchers from Brigham and Women's Hospital noted that potential savings of $229 million could have been realized from greater use of generic drugs within the Medicaid programs alone. Michael A. Fischer & Jerry Avorn, *Economic Consequences of Underuse of Generic Drugs: Evidence from Medicaid and Implications for Prescription Drug Benefit Plans*, 38 Health Servs. Res. 1051, 1055 (2003).

A recent analysis in Consumer Health Reports shows that a simple change from a branded statin such as Lipitor ($145/month) or Crestor ($125/month) to a therapeutically equivalent generic, such as Lovastatin ($18/month) or Pravastatin ($65/month) can save a consumer and their health plan hundreds of dollars each month. Consumer Reports Health, *Best Buy Drugs* at 35. (2009). Entry of one or more generic competitors results in significant savings on "[t]he daily cost of drug therapy across all products in [a] class …." Murray Aitken *et al.*, *Prescription Drug Spending Trends In The United States: Looking Beyond The Turning, Point*,

Health Affairs, 28, no. 1, w155 (2009). For instance, saving of "32 percent for lipid regulators …, 32 percent for bisphosphonates, 42 percent for selective serotonin reuptake inhibitors (SSRIs), and 20 percent for calcium-channel blockers" were seen "in the year after generic entry" to the market. *Id.* at w155-56. The "greater use of generics when available … has resulted in [an estimated] 22 percent lower pharmaceutical spending in 2007…" *Id.* at w158.

Further, consumers pay for marketing costs through the high prices of pharmaceutical prescriptions, as well as paying out for annually rising prescription costs due to price increases for older drugs, higher release prices of newer drugs, and the increased prescribing of both newer and older prescription drugs. David Gross, AARP Public Policy Institute, *Medicare Beneficiaries and Prescription Drugs: Costs and Coverage* (Sept. 2002), http://www.aarp.org/research/health/drugs/aresearch-import-656-DD77.html.

High costs take a toll on health by reducing access to important pharmaceutical therapies. A recent study shows that four in ten Americans have trouble paying for drugs, or skip prescriptions or cut pills due to cost. Press Release, Harvard School of Public Health, *Four in 10 Americans say they have trouble paying for drugs or skip prescriptions or cut pills due to cost* (Mar. 4, 2008), http://www.hsph.harvard.edu/news/press-releases/2008-releases/poll-usa-today-kaiser-harvard-prescription-drugs.html. Affordable prescription medication

is particularly important to older persons who, because of its higher rates of chronic and serious health conditions, have the highest rate of prescription drug use. As of 2005, ninety-one percent of people sixty-five or older had some sort of prescription drug-related expense. Kaiser Family Foundation, *Prescription Drug Trends* (Sept. 2008), at 2, http://www.kff.org/rxdrugs/upload/3057_07.pdf. Prescription drug spending has been growing rapidly since the 1990s, with the current rate of increase in manufacturers' prices more than doubling the rate of general inflation. *Id.*

E. Off-Label Marketing is Widespread

FDA regulations prohibit off-label marketing, i.e., the marketing of drugs for uses that have not been specifically approved. "An underlying premise of FDA regulation is that the public needs protection from the products of the profit-seeking private sector . . . [therefore] any direct promotion by a drug manufacturer of off-label drug use is strictly barred. The FDA's position is that any private industry promotion, e.g., labeling or marketing, of unapproved drug uses may result in both physicians and patients being unable to make informed and unbiased decisions." Katherine Helm, *Protecting Public Health From Outside the Physician's Office: A Century of FDA Regulation from Drug Safety Labeling to Off-Label Drug Promotion*, 18 Fordham Intell. Prop. Media & Ent. L.J. 117, 121-22 (Nov. 2007); Michelle Mello *et al.*, *Shifting Terrain in the Regulation of Off-*

Label Promotion of Pharmaceuticals, 360 Eng. J. Med. 1557 (2009). Nevertheless, pharmaceutical companies often engage in off label promotion directly to doctors.

According to a 2008 GAO report, from 2003 through 2007, FDA sent forty-two letters to pharmaceutical companies citing off-label promotion. United States Government Accountability Office, *Report to Ranking Member, Committee on Finance, U.S. Senate, Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (July 2008) ("GAO Report"), *available at* http://gao.gov/cgi-bin/getrpt?GAO-08-835. Despite this startling prevalence of known illegal off-label marketing, FDA acknowledged that due to limited resources, "it is very difficult, if not impossible, for FDA's supplementary monitoring and surveillance efforts to identify all off-label promotion that may occur." GAO Report at 17.

In a 2006 article, Steinman and his colleagues examined the off-label marketing of the drug gabapentin (Neurontin). *See* Michael A. Steinman *et al.*, *Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents*, 145 Ann Intern Med. 284 (2006), *available at* http://www.annals.org/cgi/content/full/145/4/284. Their analysis showed how one pharmaceutical company employed all the common marketing techniques at its disposal -- CME, speakers' bureaus, other physician-to-physician programs, and

conferences -- to suggest off-label uses of gabapentin. The company not only paid for research to stimulate on-label prescribing, but also employed a "publication strategy," the goal of which was to use research not as a means to gain FDA approval for new indications but "to disseminate the information as widely as possible through the world's medical literature" generating excitement in the market and stimulating off-label prescribing despite the lack of FDA approval. *Id.* The authors demonstrated that the off-label promotion scheme was effective – in 2001, after a concerted off-label promotion scheme, gabapentin had the highest proportion of off-label uses prescribed by office-based physicians, with only a small percentage of those uses based on scientific evidence of efficacy.

II. Class Actions Are Indispensable to the Vindication of Legal Rights and Deterrence

Class actions serve a number of purposes including "(1) judicial economy and efficiency; (2) protection of defendants from inconsistent obligations; (3) protection of the interests of absentees; (4) access to judicial relief for small claimants; and (5) enhanced means for private attorney general suits to enforce laws and to deter wrongdoing." 1 Albe Conte & Herbert B. Newberg, *Newberg on Class Actions* § 1:6, at 27-28 (4th ed. 2002). All of these interests are served by class action certification here, but two in particular bear comment.

First, class actions are an indispensable mechanism for redressing claims where the individual stake is relatively low and there are too many plaintiffs for

joinder.[3] As the Supreme Court stated in *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 809 (1985), class actions "permit the plaintiffs to pool claims which would be uneconomical to litigate individually." And as the Supreme Court has explained:

> The aggregation of individual claims in the context of a classwide suit is an evolutionary response to the existence of injuries unremedied by the regulatory action of government. Where it is not economically feasible to obtain relief within the traditional framework of a multiplicity of small individual suits for damages, aggrieved persons may be without any effective redress unless they may employ the class-action device. That there is a potential for misuse of the class action mechanism is obvious.

Deposit Guar. Nat'l Bank v. Roper, 445 U.S. 326, 339 (1980); *see also id*. at 338 n.9. More recently, the Supreme Court has stated:

> The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the

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[3] Even if damages for each individual in the class may vary, class actions still warrant certification. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (stating "mass tort cases arising from a common cause or disaster may, depending upon the circumstances, satisfy the predominance requirement"); *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 241 F.R.D. 435, 448 (S.D.N.Y. 2007) (surveying numerous cases and stating "The principle that supports class certification in all of these cases is the same: When liability can be resolved by a jury with a single decision that applies to the whole class, and the only individual question left to resolve relates to damages, class certification is warranted"). Moreover, even if the predominance requirement of Rule 23(b)(3) were not satisfied, the class could still be certified under Rule 23(c)(4)(A). *See In re Nassau County Strip Search Cases*, 461 F.3d 219, 230 (2d Cir. 2006) ("district courts may employ Rule 23(c)(4)(A) to certify a class on a designated issue regardless of whether the claim as a whole satisfies the predominance test").

> incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor.

Amchem, 521 U.S. at 617 (quoting *Mace v. Van Ru Credit Corp.*, 109 F.3d 338, 344 (7th Cir. 1997)). Indeed, in enacting Rule 23(b)(3), "the Advisory Committee had dominantly in mind vindication of 'the rights of groups of people who individually would be without effective strength to bring their opponents into court at all.'" *Id.* at 617 (quoting Benjamin Kaplan, *A Prefatory Note*, 10 B.C. Indus. & Com. L. Rev. 497, 497 (1969)). "Accordingly, class treatment of claims is most appropriate where it is not 'economically feasible' for individuals to pursue their own claims." *Coleman v. Gen. Motors Acceptance Corp.*, 296 F.3d 443, 449 (6th Cir. 2002); *accord Klay v. Humana, Inc.*, 382 F.3d 1241, 1271 (11th Cir. 2004) ("It also applies in situations where, as here, the amounts in controversy would make it unlikely that most of the plaintiffs, or attorneys working on a contingency fee basis, would be willing to pursue the claims individually. This is especially true when the defendants are corporate behemoths with a demonstrated willingness and proclivity for drawing out legal proceedings for as long as humanly possible and burying their opponents in paperwork and filings."); 5 James Wm. Moore *et al.*, *Moore's Federal Practice* § 23.02 (3d ed.1999) (class actions "afford aggrieved persons a remedy if it is not economically feasible to obtain relief through the traditional framework of multiple individual damage actions").

Here, many of the putative class members are non-profit health and welfare funds, created for the benefit of workers and retirees. Such funds have seen their resources dwindle as health care costs have risen and the economy stalled. Indeed, in a recent survey, the Commonwealth Fund found that fifty-three percent of private employers plan on increasing retirees' shares of their health care premiums over the next two years. Forty-three percent say they will be increasing cost-sharing for drugs; nineteen percent intend to drop retiree benefits for new hires, and twenty percent of companies plan to drop company-sponsored health benefits for active workers or existing Medicare-age retirees. The Commonwealth Fund, *Retiree Health Benefits After Medicare Part D: A Snapshot of Prescription Drug Coverage* (Sep. 2008), at 4.[4] For these funds, which are already cutting benefits, the only realistic prospect for a remedy against drug overcharges brought on by illegal marketing practices is through the class action device.

Second, class actions supplement enforcement of legal rights by government agencies which, because of their limited resources, may only prosecute the most flagrant of abuses. By allowing a named plaintiff to act as a "private attorney general," class actions not only compensate injured plaintiffs, as explained above,

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[4] *Available at* http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2008/Sep/Retiree%20Health%20Benefits%20After%20Medicare%20Part%20D%20%20A%20Snapshot%20of%20Prescription%20Drug%20Coverage/Gabel_retireehltbenefitsafterpartd_1162_ib%20pdf.pdf. (last visited June 26, 2009).

but also deter illegal conduct. *See United States Parole Comm'n v. Geraghty*, 445 U.S. 388, 403 (1980) ("In order to achieve the primary benefits of class suits, the Federal Rules of Civil Procedure give the proposed class representative the right to have a class certified if the requirements of the Rules are met. This 'right' is more analogous to the private attorney general concept than to the type of interest traditionally thought to satisfy the 'personal stake' requirement."); *Roper*, 445 U.S. at 338 (stating that class actions represent an "increasing reliance on the 'private attorney general' for the vindication of legal rights"); *see also Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 266 (1972) ("Rule 23 . . . provides for class actions that may enhance the efficacy of private actions by permitting citizens to combine their limited resources to achieve a more powerful litigation posture."); *Associated Indus. of N.Y. State, Inc. v. Ickes*, 134 F.2d 694, 704 (2d Cir. 1943) (Frank, J.) (coining the phrase private attorney general).

Class actions give individuals redress when the government does not have means, or desire, to pursue a remedy. For example, it is well-recognized that "[a] significant benefit to claimants who choose to litigate their individual claims in a class-action context is the prospect of reducing their costs of litigation, particularly attorney's fees, by allocating such costs among all members of the class who benefit from the recovery." *Roper*, 445 U.S. at 338 n.9. The cost-spreading of the class action enhances "the means for private attorney general enforcement and the

resulting deterrence of wrongdoing." *In re GMC, Pick-Up Truck Fuel Tank Prods. Liab. Litig.*, 55 F.3d 768, 784 (3d Cir. 1995).

It is by now well-known that the FDA, federal government agency overseeing the manufacturing and marketing of drugs, lacks the resources to ensure drug safety. As expressed by the Supreme Court just this term: "[t]he 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*, 129 S. Ct. at 1202. Indeed, in *Wyeth*, the Supreme Court recognized that the FDA has long had extremely limited resources:

> [In 1955] an FDA advisory committee issued a report finding "conclusively" that "the budget and staff of the Food and Drug Administration are inadequate to permit the discharge of its existing responsibilities for the protection of the American public." Citizens Advisory Committee on the FDA, Report to the Secretary of Health, Education, and Welfare, H.R. Doc. No. 227, 84th Cong., 1st Sess., 53. Three recent studies have reached similar conclusions.

Id. at 1202 n.11 (citations omitted).

The FDA has limited information available to it when it approves a new drug because a pre-approval clinical study of a new drug may only involve 1,000 to 3,000 patients that do not represent the full array of patients who will ultimately use the drug. It is often only after a drug enters the marketplace that a company will discover the drug's full ranges of risks, including risks that affect specific sub-

populations or manifest themselves only over long periods of time. In addition, more and more people are taking multiple prescriptions.[5]

The division of the FDA that monitors most drugs is the Center for Drug Evaluation and Research ("CDER"). CDER's Office of Drug Safety employs about 100 people to monitor drugs after they reach the market. In contrast, there are currently 11,000 FDA-approved drugs, including over 3,000 prescription drugs. Moreover, in the United States, doctors write in excess of 3.3 billion prescriptions per year. The FDA simply lacks sufficient resources to keep pace with new information and to take effective remedial action when a drug proves to be dangerous or inadequately labeled. *See generally* GAO Report. In contrast, CDER's Office of New Drugs ("OND"), which primarily reviews applications for new drugs and approves approximately 100 new drugs each year, employs approximately 1,000 people. Employees monitoring drugs in post-approval are supported by funding levels less than one quarter of the amount devoted to new drug approval. *Id.*

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[5] In 2006, the Union of Concerned Scientists polled FDA scientists on a range of issues. The poll found that sixty-six percent of respondents were "not at all confident" or only "somewhat confident" that the FDA adequately monitored the safety of prescription drugs after they reached the market. The poll found that forty-two percent of the survey respondents were "not at all confident" or only "somewhat confident" that the FDA's final decisions adequately assessed drug safety.

Society seeks to balance two competing interests. On the one hand, new drugs should reach the market quickly so that they can improve and save lives. Thus, for example, Congress passed the Prescription Drug User Fee Act of 1992 ("PDUFA"), Pub. L. No. 102-571, 105 Stat. 4491. PDUFA was enacted to accelerate the review of new drug applications and it placed strict timelines on the review process in exchange for user fees from the companies seeking the FDA's approval of new drugs.

On the other hand, the public and doctors should be warned about the effects of a drug on the market that is causing harm and certain drugs should be removed. However, once a drug is being sold on the market, drug companies have a significant incentive to fail to warn the public about a newly-discovered danger since warning the public, or pulling a drug from the market, can substantially harm the company's stock price. And, as explained above, the FDA does not have the resources to monitor or deter such wrongdoing. Moreover, because the harm to each individual taking the drug may be relatively small when compared with the costs of a lawsuit, the company may not be sufficiently deterred by the threat of private litigation on an individual level. Thus, private enforcement of federal and state laws through class actions "provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth*, 129 S. Ct. at 1202.

CONCLUSION

This Court should affirm the district court's decision below and permit this action to proceed as a class action.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because it contains 5,803 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii).

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Dated: June 30, 2009

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