No. 10-779

# In the Supreme Court of the United States

WILLIAM H. SORRELL, ET AL.,
*Petitioners*,

v.

IMS HEALTH, INC., ET AL.,
*Respondents*.

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

## BRIEF OF *AMICI CURIAE* AFSCME DISTRICT COUNCIL 37, HEALTH CARE FOR ALL, AND COMMUNITY CATALYST IN SUPPORT OF PETITIONERS


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## INTERESTS OF AMICI CURIAE[1]

Community Catalyst, Inc. is a national non-profit organization committed to building consumer and community voice in health care. In collaboration with local, state and national advocates and supporters, Community Catalyst advances improvements in health care policies and programs at the federal level and in over forty states. Through it's Prescription Access Litigation, LLC project ("PAL"), it seeks to promote expanded access to needed medicines while also challenging deceptive, fraudulent, or illegal promotional drug industry practices that inflate drug costs, through litigation or other legal action. PAL has built a nationwide coalition of over 130 organizations in 36 states and the District of Columbia, with a combined membership of over 13 million people, comprised of consumers, seniors, health care advocacy organizations, labor unions, health plans, and union benefit funds. PAL has facilitated its coalition members' active participation in over 30 class action lawsuits, including litigation concerning the off-label promotion of Seroquel, Zyprexa, and Neurontin.

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[1] Pursuant to this Court's Rule 37.2(a), all parties have consented to the filing of this brief. Attorneys for Petitioners and Respondents have filed blanket consents.

Pursuant to Rule 37.6, amici curiae affirm that no counsel for any party authored this brief in any manner, and no counsel or party made a monetary contribution in order to fund the preparation or submission of this brief. No person other than Amici Curiae, their members, or their counsel made a monetary contribution to the preparation or submission of this brief.

Health Care For All, Inc., ("HCFA") is a statewide Massachusetts consumer organization dedicated to promoting quality, affordable health care. Through its work in comprehensive cost containment, quality improvement and prescription drug reform, HCFA seeks to ensure that patients get the appropriate care at an affordable price. HCFA works to control prescription drug costs through minimizing conflicts of interest and enhancing independent provider education. For the past several legislation sessions, HCFA has filed legislation in Massachusetts that would limit the use of prescriber-identified information for marketing purposes because of the impact this activity has on prescription drug costs for Massachusetts residents.

AFSCME District Council 37 Health and Security Plan ("AFSCME DC 37") is a public sector union-sponsored employee health and welfare benefit plan, which provides a prescription drug benefit for covered active titles, retirees and their spouses and dependants. Contributions towards such benefits are bargained for with various municipal employers, including The City of New York, various authorities and corporations and quasi-public institutions. AFSCME DC 37 provides supplemental health benefits, including a prescription drug benefit for over 270,000 participants in all but one state in the U.S.

Amici Curiae AFSCME DC 37, Community Catalyst, and HCFA file this amicus in support of the interests of consumers and non-profit insurers in promoting access to safe, affordable, high quality

prescription drug therapies in our health care system.[2]

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[2] The amici would like to thank Karen J. Marcus for her invaluable assistance in preparing this brief.

## SUMMARY OF ARGUMENT

Since 2004, at least six of the nation's top drug makers have pled guilty to criminal charges of illegally promoting unapproved, or 'off-label' uses of prescription drugs. Combined penalties and restitution in these six federal enforcement actions exceed $6.4 billion in recoveries by State and federal health programs. A recent analysis shows that the drug industry has surpassed the defense industry as the largest violator of the federal False Claims Act, and that this type of off-label promotion accounts for over half of the drug industry's penalties from 2006 to 2010.

Documents revealed through federal and state enforcement actions and class-action litigation by consumers and health plans show that data-mined prescriber information is integral to targeting physicians for these illegal promotions of off-label drug uses. Access to daily or more frequent updates of physician prescribing records helps the drug industry improve their illegal off-label promotional messages and improve their illegal promotional marketing campaigns overall.

Marketing that promotes off-label drug uses misleads physicians, drives up costs, and threatens the quality and safety of patient care. Current regulatory and enforcement mechanisms have not deterred this illegal promotional conduct; thus broader deference to state regulation of the use of this prescriber information is warranted.

## ARGUMENT

### I. LITIGATION AND ENFORCEMENT ACTIONS HAVE REVEALED THAT DATA-MINED PRESCRIBER INFORMATION IS INTEGRAL TO ILLEGAL OFF-LABEL PROMOTIONAL CAMPAIGNS BY THE DRUG INDUSTRY.

Under federal law, prescription drugs are approved for specific uses, based upon a showing of safety and effectiveness. 21 U.S.C. §355 (a),(d) (2011). Federal law also prohibits the promotion by a manufacturer of any use of a drug that is not approved. 21 C.F.R. §202.1(e)(4)(i)(a) (2011). Promotion by a manufacturer of any use of a drug that is not FDA approved, and is not listed on the approved drug label, is called 'off-label' promotion. While it is illegal for manufacturers to promote the 'off-label' use of a drug, a physician's prescribing of a drug for an off-label use is not illegal. In order to address the needs of their patients, physicians have broad professional latitude in their prescribing decisions; but to protect patients, manufacturers are barred from interfering with this prerogative by promoting off-label uses of drugs to physicians.

Litigation by public and private parties has revealed what common sense suggests – access to the data-mined information from physicians' prescribing histories has been an integral part of the drug industry's illegal promotion of off-label uses of prescription drugs. These systematic, highly organized and management authorized off-label promotional campaigns are carried out by the drug industry in flagrant violation of the clear statutory bans on such conduct. David Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*,

Bloomberg.com, Nov. 9, 2009, available at http://www.bloomberg.com/apps/news?pid=email_en&sid=a4yV1nYxCGoA, last visited Feb. 21, 2011 (noting that drugmaker Pfizer was engaged in the illegal off-label promotion of the drugs Bextra, Lyrica, Geodon, and Zyvox in 2004 even as the company was negotiating a settlement with the Department of Justice concerning the illegal off-label promotion of the drug Neurontin.)

Litigation and enforcement actions by public and private parties concerned with ending these illegal off-label promotions have made otherwise secret internal drug industry documents publicly available. Among many other things, these documents reveal two critical facts. The drug industry uses data-mined physician prescribing information to: 1. target specific physicians for illegal off-label promotions; and 2. increase the effectiveness of their illegal promotional activity.

*A. Off-Label Promotion of Neurontin using Data-Mined Prescriber Information.*

The Department of Justice's $430 Million settlement with Pfizer in May of 2004 included a guilty plea to felony misbranding to resolve the criminal and civil charges concerning the illegal off-label promotion of the drug Neurontin. Press Release, U.S. Dep't. of Justice, Warner Lambert to Pay $430 Million to Resolve Criminal and Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), *available at* http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm (hereinafter "D.O.J. Press Release May 13, 2004").

The breadth of off-label promotion by Neurontin's manufacturer Warner-Lambert, and then Pfizer,[3] was astonishing. Neurontin was approved by the FDA for the "adjunctive or supplemental anti-seizure use by epilepsy patients". Warner-Lambert and Pfizer "aggressively marketed [Neurontin] to treat a wide array of ailments for which the drug was not approved [including] bipolar mental disorder, various pain disorders, Amyotrophic Lateral Sclerosis (ALS, a degenerative nerve disease commonly referred to as Lou Gehrig's Disease), attention deficit disorder, migraine, drug and alcohol withdrawal seizures, [and] restless leg syndrome . . . ." *Id.*

1. Pfizer routinely used data-mined information to assess their illegal marketing plans.

Pfizer's Neurontin marketing plan entitled "Neurontin 2003 Operational & Tactical Plan, *Advance Copy*" reveals that Pfizer used prescriber data to chart "Neurontin uses by indication" including its off-label uses to treat "bi-polar [disorder,] Chronic Back & Neck [pain, and] Neuropathic Pain." Plaintiff's Exhibit 239 at 13, Trial Feb. 22, 2010, *Kaiser v. Pfizer*, Civ. No. 10-10981-PBS. (D. Mass.)[4] This document also stated

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[3] Pfizer purchased Warner-Lambert in June of 2000. See Mathew Herper, *Pfizer's Warner-Lambert Acquisition Has Side Effects,* Forbes.com, June 16, 2000, at http://www.forbes.com/2000/06/21/mu5.html, last checked Feb. 25, 2011. .

[4] *Available at* www.prescriptionaccess.org/docs/NeurontinKaiserTrialExhibit239, last visited Feb. 28, 2011.

that Pfizer's medical marketing team "will be continuing to monitor the [anti-epileptic drug] market and Neurontin's performance in neuropathic pain and epilepsy through the secondary audits (IMS) . . . ." *Id*. at 20.

Pfizer used data-mined prescriber information to track the number of Neurontin prescriptions by physician specialty. Plaintiff's Exhibit 129[5] at 17, *Kaiser v. Pfizer*, Civ. No. 10-10981-PBS (D. Mass. Feb. 22, 2010). Combined with other data on the number of salesperson visits, or "details" per specialty, *id*. at 92, 96, and the number of free drug samples distributed by specialty, *id*. at 98, Pfizer could better evaluate how their promotional activities correlated with increased prescribing by specialty, *Id*. at 99, and overall. *Id*. at 100. Pfizer also used prescriber data to track drug sales. By the end of 2000, the FDA approved use to treat epilepsy accounted for 11% of total use, while off-label uses accounted for the remaining 89%. *Id*. at 16.[6]

These documents illustrate how this data-mined prescriber information was used by Warner-Lambert

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[5] *Available at* www.prescriptionaccess.org/docs/NeurontinKaiserTrialExhibit129, last visited Feb. 28, 2011.

[6] Exhibit 129, page 16, lists "Scott Levin PDDA, Drug Uses, MAT Jul 94-00" as the source of the prescriber data. Scott-Levin was a market research firm that merged with Verispan in 2002. (see Matthew Arnold, *Verispan acquired by data rival SDI*, July 29, 2008, Medical Marketing & Media, available at http://www.mmm-online.com/verispan-acquired-by-data-rival-sdi/article/113065/#.) The abbreviation "PDDA" stands for the "Physician Drug & Diagnosis Audit" report. *Id*.

and then Pfizer to evaluate, monitor, and improve their sales tactics, particularly for off-label uses.

2. Pfizer also used data-mined prescriber information to target doctors to receive illegal off-label promotional communications and kick-backs.

In entering the 2004 Neurontin settlement, Pfizer agreed to plead guilty to the facts recited in the Department of Justice's "Information" filed in the criminal prosecution. Settlement Agreement between the Office of the Inspector General and Pfizer (May 11, 2004), *available at* http://www.contractormisconduct.org/ass/contractors/188/cases/1290/1834/pfizer-eurontin_settlement.pdf. Therein, the Department of Justice asserted that Warner-Lambert invited "certain doctors . . . based upon their history of writing a large number of prescriptions for Neurontin or similar drugs" to attend a "consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida" in April of 1996. Information in *United States v. Warner-Lambert Co. LLC* ¶ 25-26,, ¶ Criminal No. 04-10150-RGS (D. Mass. May 13, 2004) May 13, 2004) ("Information"), at ¶. 25-26. The physicians were identified through data-mined prescriber information concerning Neurontin prescriptions they had written.

Warner-Lambert not only provided these identified physicians with "paid accommodations and meals for the invited doctors and their spouse or guest, and . . . an honorarium" but also organized Warner-Lambert funded presentations promoting off-label uses of Neurontin during the meeting. *Id*. at ¶ 26-28. This included off-label promotion of uses to treat pain and other indications not approved by the FDA. *Id*. Following the meeting, Warner-Lambert

then identified these specific physicians who had received the "hard-hitting message about Neurontin" to their marketing sales force, with instructions and worksheets "intended to be used to gauge the effect of the meeting on the subsequent prescribing by doctors who had attended." *Id*. at ¶ 29.

This Department of Justice investigation provided a rare glimpse into the marketing plans by drug manufacturers with respect to their monitoring of physicians and their prescribing patterns. This example illustrates the two insidious ways manufacturers can use prescriber data. First, Warner-Lambert identified specific physicians to receive direct financial payment (honoraria) and other inappropriate gifts (accommodations). These physicians were presented with communications that illegally promoted off-label drug uses. Next, Warner-Lambert used data-mined prescriber information to track these doctors' prescribing behavior, enabling Warner-Lambert to assess the effectiveness of their promotional tactics.

The off-label promotion of Neurontin arguably expanded after Pfizer, the largest supplier of drugs in the US[7] acquired Warner-Lambert in 2000.[8] Before the merger, a Pfizer Vice President marveled at the numerous medical conditions Neurontin was being used for, calling it "the 'snake oil' of the twentieth century." Kaiser's Motion to Admit Wahlberg Document at 4, Mar. 14, 2010, *In re*

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[7] *FACTBOX-The 20 largest pharmaceutical companies*, Reuters, Mar. 26, 2010.

[8] D.O.J. Press Release May 13, 2004.

*Neurontin Marketing and Sales Practices Litigation*, Civ. No. 04-cv-10981-PBS (D. Mass.).[9]

By 2003, Pfizer's marketing team was fully engaged in continuing the illegal off-label promotional campaign initiated by Warner-Lambert. Pfizer's internal marketing department documents depicted Neurontin as a 'witches brew' that could be marketed for many indications that were unapproved. Jim Edwards, *PowerPoint Fail: Pfizer Slideshow Depicts Neurontin as a Witch's Brew*, BNET (Apr. 14, 2010), http://www.bnet.com/blog/drug-business/powerpoint-fail-pfizer-slideshow-depicts-neurontin-as-a-witch-8217s-brew/4605.

*B. Eli Lilly's Off-Label Promotion of Zyprexa.*

In January of 2009, the Department of Justice announced a record criminal fine of $515 Million assessed against drugmaker Eli Lilly ("Lilly") in settlement of the investigation of numerous illegal practices including the illegal off-label promotion of the drug Zyprexa for "treatment of elderly patients for such things as sleep disorders and dementia." Press Release, U.S. Dep't of Justice, Pharmaceutical Company Eli Lilly to Pay Record $1.415 Billion for Off-Label Drug Marketing (Jan. 15, 2009), http://www.justice.gov/usao/pae/News/Pr/2009/jan/lillyrelease.pdf (hereinafter "D.O.J. January 2009 Press Release").

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[9] July 21, 1999 email from Dr. Chris Wohlberg, available at http://i.bnet.com/blogs/snake-and-oil.jpg, last checked Feb. 25, 2011.

Of particular concern was the fact that Lilly promoted the specific off-label use of Zyprexa for the treatment of dementia suffered by elderly patients. Lilly did so with knowledge that that their internal own studies had failed to show that Zyprexa was effective to treat dementia, and that the use of Zyprexa could be linked to an increased risk of death in this particularly vulnerable subpopulation. *See* D.O.J. January 2009 Press Release; *see also* Margaret Cronin, Fisk et al., *Lilly Sold Drug for Dementia Knowing It Didn't Help, Files Show*, Bloomberg.com, June 12, 2009.

Documents released in the private sector litigation concerning the same illegal off-label promotional conduct show how prescriber information was used in this marketing plan. One Lilly document shows how the manufacturer used data-mined prescriber information to group physicians for marketing purposes based on their prescribing histories. Eli Lilly, "2003-2004 Zyprexa U.S. Marketing Plan" at 38 (labeled as "ZY203452256") available at http://www.zyprexalitigationdocuments.com/documents/Confidentiality-Challenge/Docs-challenged-in-10-3-list/126-ZY205205603.pdf, (erroneously posted on the website with the label "125. Performance Summary; dated Jan. 2000").

Lilly's groupings created five categories of physicians ranking them from highest to lowest priority. The top priority physicians were described as "High Flyers." Prescriber data identified and classified these physicians as the"[e]arliest adopters]" of new medications, and the "highest volume" prescribers, comprising "16% of docs" but accounting for "30% of [potential sales]." *Id*.

In contrast, Lilly's lowest priority physicians were called "Systematic Conservative[s]". *Id*. These physicians were those who were "concerned about safety", used a "[r]egular systematic approach" to treatment plans for their patients and prescribing "indication[s] [were] focused with on-label use." *Id*. Not surprisingly, these physicians were also characterized as "the "slowest adopter[s]" who wrote the "lowest volume" of prescriptions.

Thus the access to prescriber history data allowed Lilly to engage in sophisticated analyses to pre-determine which physicians would be the most willing to use a prescription for an unapproved and unproven use, and then target those physicians for promotions of the off-label uses of Zyprexa.

Lilly further refined their marketing of Zyprexa to highlight to physicians the specific patient characteristics associated with the treatment of major depression, Alzheimer's with psychosis, Alzheimer type dementia, and mild dementia, all off-label uses of Zyprexa. Id. at 39, 50. These marketing plans enabled Lilly to increase sales of Zyprexa to vulnerable elderly patients despite known medical risks.

*C. Pfizer's Off-Label Promotion of Bextra.*

In September of 2009, Pfizer admitted to the off-label promotion of Bextra, and settled criminal and civil investigations by paying "a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter." Press Release, U.S. Attorney's Office District of Massachusetts, Pharmacia &. Upjohn Company Inc. Pleads Guilty to Fraudulent Marketing of Bextra (Sept. 15, 2009),

*available at* http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Sept 2009/PharmaciaPlea.html (hereinafter "U.S. Attorney Sept. 2009 Press Release").

Pfizer paid an additional $1.1 billion in other civil penalties to settle the U. S. government's investigation of charges related to the illegal off-label promotion and illegal kick-backs of four drugs: Bextra, Geodon, Lyrica, and Zyvox. *Id*.

Specific details revealed that Pfizer used data-mined prescriber information to target physicians for illegal off-label promotions. Data-mined prescriber information concerning the competing drug Vioxx was used in an illegal scheme by "[Pfizer]'s sales force [to] create[] sham physician requests for medical information in order to send unsolicited information to physicians about unapproved uses and dosages [of Bextra]." *Id*.

These revelations, and related documents[10], show how Pfizer's marketing sales force used the data-mined prescriber data related to a competing drug to target specific physicians to receive illegal off-label promotional communications concerning Bextra. U.S. Attorney's Office, Pfizer Settlement, Farina Trial Exhibit 17C, *available at* http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Pfizer/exhibits/Farina%20Trial%20Exhibit%2017C.pdf. Without this

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[10] Numerous documents available at "Pfizer Settlement," United States Attorney's Office – Welcome to the District of Massachusetts, http://www.justice.gov/usao/ma/Pfizer.html (last visited Feb. 28, 2011).

information about past prescribing conduct, Pfizer would not have been able to target their illegal 'off-label' mailed marketing materials promoting an off-label use.

## II. STATES HAVE COMPELLING INTERESTS IN PREVENTING WIDESPREAD ILLEGAL OFF-LABEL PROMOTION, WHICH LOWERS QUALITY OF CARE, AND RAISES HEALTH CARE COSTS

Estimates of off-label use of prescription drugs range from 21% to 40% of all prescriptions. Center for Health and Pharmaceutical Law & Policy, Seton Hall Univ. School of Law, *Drug and Device Promotion: Charting a Course for Policy Reform*, Jan. 2009, footnote 62 (*citing* David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians,* 166 Archives of Internal Med. 1021 (2006); footnote 63 (*citing* S. Green, *False Claim Act Liability for Off-Label Promotion of Pharmaceutical Products*, *Penn State Law Review* 110 Dick. L. Rev., No. 1, (2006): 41-68 (2006).

Off-label drug use could amount to between 1,452,411 and 3,873,096 of the 9,682,741 prescriptions filled in Vermont pharmacies in 2009.[11]

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[11] Calculated as either 21% or 40% of 9,682,741 total prescriptions filled at retail pharmacies in Vermont. *See* The Kaiser Family Fund, "Total Retail Sales for Prescription Drugs Filled at Pharmacies, 2009," Statehealthfacts.org (2010), http://www.statehealthfacts.org/comparemaptable.jsp?ind=266 &cat=5, last checked Feb. 21, 2011..These totals do not include other prescription medications provided through mail order distribution or those provided to patients in hospitals or other in-patient settings.

Hundreds of Thousands of Vermont consumers are likely impacted by this volume of prescriptions.

Some off-label uses of prescription drugs are critical to patients, such as the treatment of pediatric populations, or uses in the treatment of cancer. However, a 2006 study concluded that 73% of overall off-label uses, and 90% of all psychiatric off-label uses, lack a finding that the drug is an effective treatment. Center for Health and Pharmaceutical Law & Policy, at footnote 67 (citing Radley, *supra,* at 1021-26.)

Additionally, a 2009 survey found that a "substantial minority of physicians erroneously believed that certain off-label uses of prescription drugs were approved by the Food and Drug Administration." G. Caleb Alexander, *Off-Label Use Often Not Evidence-Based: Physicians Lack Knowledge Of Off-Label Drug Use And FDA Approval Status, Study Finds*, ScienceDaily (Aug. 23, 2009), http://www.sciencedaily.com/releases/2009/08/090821135011.htm. The study's authors conclude that physician's "mistaken belief[s about FDA approval] could encourage them to prescribe these drugs, despite the lack of scientific evidence supporting such use." *Id*.

Alone, these facts create a grave concern that off-label prescribing creates an alarming potential for widespread ineffective, inappropriate, and potentially dangerous prescription drug use, and wasteful spending. But in light of the pharmaceutical industry's widespread conduct to drive profits by illegally promoting the off-label uses of many prescription drugs, consumers and health plans in Vermont and elsewhere are seeing an

emerging public health crisis of significant proportions.

*A. Off-Label Promotion is Widespread.*

Between 2004 and 2009, seven of the nation's largest drug manufacturers paid "$7 billion in fines and penalties" related to off-label promotions, with six "companies admit[ting] in court that they marketed medicines for unapproved uses." Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*, Nov. 9, 2009.

A more recent study concludes that the drug industry's 'unlawful promotion', which is primarily off-label promotion, totaled at least $3.3 billion, or 53% of all the drug industry's financial penalties collected by the federal government under the False Claims Act from 2006 to 2010. Public Citizen, *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991 to 2010*, Dec. 16, 2010, at 18; Figure 5. Pharmaceutical Industry Financial Penalties by Type of Violation, 1991-2010, available at http://www.citizen.org/documents/rapidlyincreasingcriminalandcivilpenalties.pdf, last visited Feb. 14, 2011. This widespread conduct has helped the drug industry supplant the defense industry as the leader in violations of the federal False Claims Act since 2007. Id. at 12. This study's authors caution that the decline in pipeline of new drug products could create "pressure [upon the marketing departments of drug manufacturers] to maximize sales of existing products by any means, including by illegally promoting off-label use. *Id*. at 19.

For instance, in litigation by the private-sector insurers, a Harvard-University health economics expert estimated that the illegal off-label promotional conduct caused as many as 43 million prescriptions for off-label uses of Neurontin to be written. Declaration of Meredith Rosenthal, Estimate of Units Paid For by Neurontin Endpayers that Resulted from Alleged Fraudulent Marketing, at ¶ 55.[12] *available at* http://www.pharmalot.com/wp-content/uploads/2008/10/neurontin-2-rosenthal.pdf, last visited Feb. 27, 2011.

The potential scope of illegally promoted drug sales, and the resulting financial and therapeutic harm is staggering. While the recent increased rate of federal and state enforcement actions concerning misbranding of drugs through illegal off-label promotional conduct signals an increasing priority for state and federal enforcement, it also shines a light on a regulatory system that is unable to prevent this widespread illegal conduct. For instance, the January 2009 record-breaking $1.4 billion settlement concerning the off-label promotion of Zyprexa amounts to only 4% of Eli Lilly's gross sales revenue for that drug. Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*, Nov. 9, 2009. The subsequent record-breaking $2.3 Billion settlement and fines paid by Pfizer in September 2009 amounted to 16% of Pfizer's nationwide profits from the sale of the four illegally promoted drugs subject to that enforcement action and settlement.

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[12] See also "Neurontin On- and Off-Label Use" at 48; "Neurontin Detail Spending by Physician Specialty Category" at 57; and "Summary of Regression Results Showing Prescriptions Subject to Fraud for Entire Class Period" at 93.

These fines may be seen as little more than a 'speeding ticket' by an industry making record profits from public and private sector payors alike.

*B. Off-Label Promotion Creates Therapeutic Risks or Harms to Patients.*

The off-label use of drugs attributable to illegal promotional conduct raises significant patient safety concerns because drug manufacturers have not demonstrated the safety of such off-label uses as required under federal law.

For example 27, 2011.

Similarly, Zyprexa was aggressively promoted for off-label use by Lilly to treat dementia. D.O.J. January 2009 Press Release. However, the FDA never approved Zypreza as safe and effective for those uses, and Lilly's own internal studies revealed that this particular off-label use resulted in greater risks of death and other adverse events in senior populations. Cronin, *Lilly Sold Drug for Dementia Knowing It Didn't Help*, June 12, 2009.

Other illegal promotions of off-label pediatric uses of anti-psychotic and anti-depressant drugs (e.g. Lexapro, Celexa, Paxil) have exposed populations of these vulnerable patients, youth under 18 years of age, to significant risks. In the case of Paxil, prescribed as an anti-depressant, information about the risks of suicidal thoughts when used off-label by patients between 12 and 18 years of age prompted the FDA to add a black-box warning to its label. *New warning label ordered for antidepressants -- Children and teens at increased risk for suicide, says FDA*, MSNBC.com, Oct. 15, 2004.

These off-label uses exposed this particularly vulnerable population – children suffering from depression – to significantly higher safety risks.

In addition to safety concerns, off-label promotions can create misinformation or confusion by prescribers concerning a drug's effectiveness. This can deprive patients of alternative care, such as an alternative drug, or an alternate type of therapy – physical therapy, psychotherapy, diet, exercise, lifestyle change, etc.

*C. Off-Label Promotion Leads to Financial Harms to the Public and Private Sector Payors, and Consumers.*

Illegal promotional activities targeting physicians will result in false or inaccurate impressions concerning a drug's safety or effectiveness. These impressions leave State programs, private health plans, and consumers exposed to ongoing costs of inappropriate off-label drug prescribing.

For example, the cost of illegally promoted Neurontin use to insurers, both public and private, was significant. The Department of Justice noted that "[f]rom 1994 to 2002, sales of Neurontin to the Department of Veterans Affairs jumped from $287,000 to $43.2 million." Dept. of Justice, Press Release, May 13, 2004. For the private sector, a drug that Warner-Lambert had predicted would earn only $500 Million in gross sales over its lifetime, was aggressively promoted to become a block-buster drug, selling more $2.7 billion in 2003, the last full year of sales before the settlement with the U.S. Government was announced. Julie Schmit,

*Drugmaker Admitted Fraud, but Sales Flourish*, USA Today, Aug. 16, 2004.

## III. ILLEGALITY AND PENALTIES ARE INSUFFICIENT DETERRENTS, WARRANTING BROADER REGULATION TO PREVENT ILLEGAL OFF-LABEL PROMOTIONAL CONDUCT

The revelations of the drug industry's off-label promotion since 2004 argue strongly that existing regulatory resources and mechanisms to prevent this illegal conduct are inadequate. Further, current trends in legal decisions may be removing the threat of private sector litigation by consumers or health plans as a deterrent of this illegal conduct. *See, e.g.*, Memorandum and Order, Doc. # 3152, Dec. 10, 2010, *In re Neurontin Marketing and Sales Practices Litigation*, Civ. No. 04-cv-10981-PBS (D. Mass Order, Sept. 10, 2010, *In re: Zyprexa Products Liability Litigation*, 09-0222-cv, 2nd.Cir, (reversing class certification and dismissing claims by insurers seeking to recover their costs covering prescriptions written by physicians receiving fraudulent or off-label promotions.)

With the potential threat of litigation by the private sector diminished, deterrence is reduced. As the widespread scope of the practice of illegal off-label promotion by the drug industry becomes increasingly apparent, state regulation, which protects patients in both public and private plans, to better prevent the already legally prohibited conduct is justified.

The continually emerging revelations of off-label promotion suggest that the real scope of this illegal conduct may be far more widespread than previously

thought. For instance, the recent Department of Justice enforcement actions concerning Zyprexa, Neurontin, Bextra, and other drugs were the result of whistleblowers filing *qui tam* litigation under seal. Duff Wilson, *Side Effects May Include Lawsuits*, N.Y. Times (Oct. 2, 2010), *available at* http://www.nytimes.com/2010/10/03/business/03psych.html. More than "1,000 False Claims Act lawsuits are still under way, most of them focused on health care and many on lucrative antipsychotic drugs" like Seroquel, Zyprexa, and Risperidol, which have been linked to illegal off-label promotional conduct. *Id*.

The revelations of the drug industry's off-label promotion since 2004 argue strongly that existing regulatory resources and mechanisms to prevent this illegal conduct are inadequate.

## CONCLUSION

Upholding the State of Vermont's ban on the use of this information in marketing of drug products will help promote health, control costs, and prevent illegal conduct that is a widespread problem in the prescription drug market. In light of the highly beneficial economic and therapeutic impacts of the law upon consumers and health plans, we pray the Court will reverse the underlying decision in the Second Circuit, and uphold the Vermont law.

Respectfully submitted,

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