

WHERE'S THE RAGE? CASE MADE FOR DRUG INDUSTRY REFORM!



Ann Woloson
Executive Director

AS THE HEALTH care reform debate continues, policy makers need to remain mindful of the manner in which the pharmaceutical industry continues to prioritize profits over patients. The recent announcement about the \$2.3 billion settlement with pharmaceutical giant Pfizer, the largest health care fraud settlement in the Justice Department's history, represents much more than a wake-up call to the industry. The settlement represents the largest fine ever imposed in a US criminal prosecution. Consumers, prescribers, and policy makers must consider what the settlement means, particularly in the context of health care reform in the effort to improve access to safe and affordable care, including prescription drugs.

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Specifics of the settlement are enough to make most of us cringe. The settlement alleges Pfizer promoted the use of several of its drugs for unapproved purposes. It also contends the drug giant paid illegal kickbacks in the form of cash, high-priced dinners, and weekend getaways to induce prescribers to prescribe its drugs. Drugs named in the settlement include Bextra, Geodon, Zyvox, Lyrica, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec.

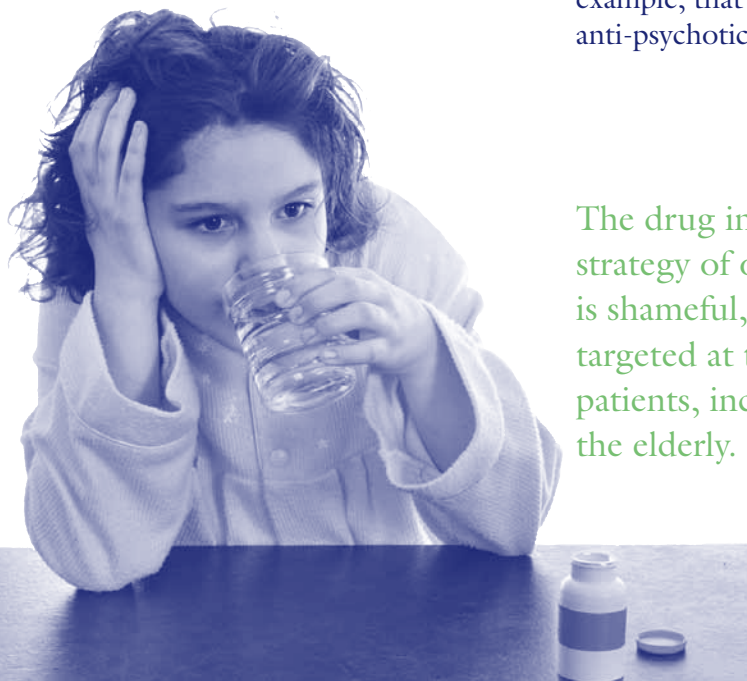
While prescribing for an unapproved or "off-label" use is legal and merited in some cases, drug companies are not allowed to promote drugs for such purposes. The industry's relentless strategy of off-label promotion is shameful, especially when it's targeted at the most vulnerable patients, including children and the elderly.

The settlement contends, for example, that Pfizer marketed the anti-psychotic drug, Geodon, for

a variety of unapproved conditions seen in children and adolescents, including attention deficit disorder, autism, and depression. Studies have linked the drug to significant weight gain and chronic disease, including diabetes. Another drug named in the settlement, Bextra, approved for osteoarthritis and rheumatoid arthritis, but marketed for acute pain and at dosages not approved by the FDA, was pulled from the market after it was associated with increased risks of heart attack and stroke.

It doesn't stop there. While the details of the \$2.3 billion settlement were still emerging, another Pfizer settlement, totaling \$33 million, was announced. This other settlement with 42 states and the District of Columbia was to resolve "state civil consumer protection allegations" regarding past activities relating to the promotion of Geodon. Once again, the drug was marketed for a number of off-label uses, including pediatric use and at dosages not approved by the FDA.

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Choices Offers Strategies for Effective Prescription Drug Reform

Industry analysts recently announced that pharmaceutical companies have raised the wholesale prices of brand-name prescription drugs by about 9 percent in the last year (according to “Drug Makers Raise Prices in Face of Health Care Reform” published in the *New York Times* on November 15, 2009). The news that the industry has been raising its prices at the fastest rate in years should come as no surprise. Prescription drug sales in the US increased from \$40.3 billion in 1990 to \$286.5 billion in 2007, as the industry shifted its orientation from focusing on research and development to marketing.

PPC recently collaborated with the Maine Center for Economic Policy (MECEP) to publish a report on prescription drug policy reform that takes issue with the industry’s aggressive marketing tactics that have contributed to the dramatic increase in prescription drug use and costs in recent years. *Choices: A New Kind of House Call Delivers Science Not Sales: Prescription Drug Reform that Works*, written by PPC policy analyst Jennifer Reck, examines the steps being taken to curb undue industry influence, such as evidence-based prescribing as a means to improve access to safe, effective prescription drugs,



“A New Kind of House Call” is available online at www.policychoices.org/ProjectsAcademicDetailing.shtml.

while containing costs.

The collaboration between MECEP and PPC grew out of an initiative, funded by the Maine Health Access Foundation, to develop and advocate for policy strategies to help contain sky-rocketing health care costs. Through this initiative, MECEP is working to improve transparency in health care coverage so consumers can make better informed choices and PPC is promoting prescribing practices based on science and current research from sources independent of the pharmaceutical industry.

As an alternative to the drug industry’s tactics, PPC promotes prescriber education programs which send trained clinicians to physicians’ offices to present the best available,

objective scientific evidence in a given therapeutic area. Unlike pharmaceutical sales representatives, who are paid on commission to get prescribers to write prescriptions for their products, prescriber educators are not trying to sell anything. They provide independent, evidence-based information.

In addition, PPC is working to engage consumers in prescribing decisions as a way to help to offset the relentless direct-to-consumer advertising conducted by drug companies. PPC has partnered with *Consumer Reports Health Best Buy Drugs*™ to provide consumers with balanced, consumer-friendly information about prescription drugs.

Maine’s Prescriber Education Program

The Maine Independent Clinical Information Service (MICIS), launched in August 2009, is a free, voluntary educational service for Maine prescribers. MICIS is administered by the Maine Medical Association in partnership with the Department of Health and Human Services under the direction of a physician-led advisory committee. (PPC policy analyst Jennifer Reck is an advisory committee member.)

MICIS employs two part-time academic detailers who are both physician assistants with clinical experience. The academic detailers received training from the Independent Drug Information Service (iDiS), the nonprofit led by Dr. Jerry Avorn of Harvard Medical School/Brigham and Women’s Hospital who, along with others, developed and researched the concept of academic detailing.

The program’s initial educational module covers Type II Diabetes and will be followed by a module on anti-platelet therapy. Half-hour to one-hour visits can be scheduled on a one-on-one basis, or a small group setting is also an option. Prescribers participating in an academic detailing visit may be eligible to receive continuing medical education (CME) credits.

BOARD PROFILES



ROY M. TAKUMI

Roy Takumi is the state of Hawaii's representative for the 36th District, which includes the Pearl City, Momilani, Pacific Palisades, and Manana areas on the island of Oahu. He was first elected in 1992. He is chairman of the House education

committee, and, as such, much of his legislative work has been in K-12 education. In recent years, Takumi has worked to pass bills to improve the quality of charter schools, expand online learning opportunities, establish the framework for universal pre-school, and enable schools to have far more flexibility, autonomy, and authority over their budgets.

Takumi is also a member of the House higher education, labor, public safety, and transportation committees. He has worked to pass bills ranging from divestment of the retirement system in companies that do business in Darfur to a state version of the Employee Free Choice Act to the banning of shark fin harvesting.

Takumi was a proponent of the bill that eventually became the Hawaii Rx law in 2002. Hawaii Rx was modeled after Maine Rx; both are programs that were established to reduce prescription drug prices. The Hawaii Rx program was named a finalist for the Council of State Governments Innovations Award in 2005.

Over the years, Takumi has also introduced bills on drug pricing, confidentiality, detailing, and disclosure of clinical trials. In 2007, he helped to pass a bill similar to Illinois I-Save Rx program over the governor's veto. (I-Save Rx is a mail order pharmacy program that was developed by the state of Illinois to provide access to lower cost prescription drugs from Canada, the United Kingdom, and Ireland.)

In addition to his legislative duties, Takumi serves as communications specialist for the Hawaii State AFL-CIO. He earned his master's degree in public administration from the University of Hawaii.



PETER SHUMLIN

Educator and politician Senator Peter Shumlin, who recently announced his candidacy for governor of Vermont, has served in public life for almost 30 years. He earned his bachelor's degree at Wesleyan University. Then, when he was 24 years old, he began a seven-

year stint as Chair of the Putney Selectboard. He served in the Vermont House from 1989 to 1992 and the Vermont Senate from 1992 to 2002. After his first term in the Senate, he was elected Senate Minority Leader. After one term as Minority Leader, he was elected President pro tem for the following six years. Then, after a four-year absence, Shumlin returned to the Vermont Senate in 2006 and was elected by his colleagues to serve again as President pro tem. He currently serves on the appropriations and transportation committees and chairs the Senate rules and joint rules committees.

In addition to his work in politics, Shumlin serves as a director, along with his brother, Jeffrey, at Putney Student Travel, a business started by their parents that offers education travel programs to secondary school students.

Among many other issues, Shumlin cares deeply about economic development, equal rights, renewable energy, and access to affordable health care. He focuses on creating jobs through developing Vermont's green energy economy, bringing affordable and quality health care to all Vermonters, reducing the cost of prescription drugs, and mental health parity. He is a founding member of the National Legislative Association on Prescription Drug Prices (NLARX), an organization of state legislators who seek to work jointly across state lines to make prescription drugs more affordable and accessible. Shumlin was instrumental in the passing of Vermont law that mandates disclosure of gifts to physicians and health care organizations to ensure greater health care transparency in the state.

BOARD MEMBER NEWS

PPC board member Kevin Outterson had the article, "How Medicare Could Get Better Prices on Prescription Drugs," published in the September/October 2009 issue of *Health Affairs*. The article examines options for drug pricing

policy reform, including value-based pricing; expansion of generic and therapeutically equivalent substitution; increased formulary diversity; importation; and limited antitrust waivers. (The latter options may reduce federal spending without

direct government price negotiations.) The article states that these options should be considered as part of health care reform. Outterson, an associate professor at Boston University School of Law whose research focuses on global pharmaceutical

markets and health disparities, co-authored the article with Aaron Kesselheim, an instructor in medicine at Harvard Medical School and an associate physician at Brigham and Women's Hospital.

VERMONT RAISES THE BAR IN GIFT BAN LAW

Sharon Treat, Legal Project Director

IN THE FINAL HOURS OF THE 2009 SESSION, the Vermont Senate and House passed a sweeping law to close loopholes in the state's existing gift and payment disclosure law and ban most gifts from manufacturers of prescription drugs, medical devices, and biological products. The gift ban includes food and free meals, a First-in-Nation provision.

The law, S.48, which took effect on July 1 of this year, mandates full disclosure of allowable gifts to physicians, health care organizations, nonprofit groups, and state-funded academic institutions. It also insures a higher degree of transparency in the state's health care system. Vermont joins Massachusetts, which enacted a comprehensive gift ban and disclosure law in 2008, and Minnesota, which enacted a more limited gift ban in 1993.

Exempted from the gift ban are samples and labels; short-term loans of medical devices; clinical articles, medical journals, and other items that serve a genuine educational function for the benefit of patients; scholarships for medical students, residents, and fellows to attend major conferences; and rebates and discounts provided in the normal course of business. Exceptions to the disclosure requirements include royalties and licensing fees, rebates and discounts, and samples of prescription drugs. Special rules apply to the disclosure of clinical trials.

Despite these exceptions, the Vermont legislation is significantly more comprehensive than pending transparency legislation in Congress, the Physician Payments Sunshine Act. Besides Massachusetts and Minnesota, other states with transparency laws—none of which are as effective as the new Vermont law and none of which include gift bans—are the District of Columbia, West Virginia, and Maine.

“The new law allows consumers going to their physician to know whether their doctor is taking money from the pharmaceutical companies,” said Vermont Senate president pro tem and PPC board member Peter Shumlin, a sponsor of the bill. “It allows for greater patient and consumer empowerment and, in these difficult economic times, is a good step toward addressing our rising health care costs.”

Despite heavy lobbying by the pharmaceutical and biotech industries, the legislation received broad bipartisan support and was supported by such organizations as the Vermont Association for Mental Health, Vermont Medical Society, and Vermont Public Interest Research Group.



Are free samples “a boon to doctors trying to provide medicines to low-income patients and those without insurance, or a marketing ploy that distorts the way health care is delivered?”

Although Vermont already required disclosure of many gifts and payments to prescribers, the new law closes a trade secret loophole which resulted in most data being submitted in aggregate form, with the public in the dark about whether their own providers accepted gifts and payments. According to Vermont legislative staff, only 17% of the requested information was publicly available under the former law.

For several years, the Vermont Attorney General has issued annual reports analyzing the data collected under the previous law. While incomplete, the data was nevertheless eye-opening. In 2008, makers of medical products spent about \$2.9 million on marketing to health care professionals in Vermont, according to the most recent report from Attorney General William Sorrell. Of Vermont's 4,573 licensed health care practitioners, almost half received remuneration, including payments for lectures, meals, or lodging from pharmaceutical companies.

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ONCE AGAIN, PPC IS LEADING THE WAY IN SUPPORT of thoughtful policy that promotes evidence-based prescribing—this time in the courts. It isn't enough to pass laws and fund programs—if drug makers and other industry groups challenge these initiatives in court, good policy can go down the drain without a vigorous defense.

New Hampshire's law banning the marketing use of certain "data mined" prescriber information has already been upheld by the First Circuit Court of Appeals (with the US Supreme Court refusing to review the result), and the law is finally being implemented. Vermont's law, which bans marketing uses of individually identifiable prescriber information unless the health provider "opts in" and grants permission, is still tied up in the courts, despite a Federal District Court decision upholding the law.

In October, the Second Circuit Court of Appeals in New York City heard oral argument in the data mining industry's appeal, and PPC had a major role shaping the legal arguments the court is now considering. PPC filed a "friend of the court" legal brief supporting Vermont, joined by AARP, Community Catalyst, and NLARx (National Legislative Association on Prescription Drug Prices).

"The insertion of the pharmaceutical company into the monitoring and influence of the patient's treatment is an invasion of privacy—one that directly affects treatment courses through influences that are nearly impossible for the patient to detect," said attorney Meredith Jacob, who is pharmaceutical policy fellow at American University's Washington College of Law and part of PPC's legal team. Jacob also noted that the use of "anonymous" patient level data and physician-identifiable prescription data "skews prescribing choices and increases costs by allowing marketers to target individual, though unnamed, patients through data-driven marketing to physicians."

Kevin Outterson, a PPC board member and Boston University School of Law professor, also defended Vermont's law. Outterson, joined by two other law professors, authored a brief on behalf of physicians,

"Targeted marketing using prescriber-identifiable data causes unnecessary, expensive, and potentially risky over-prescription of new drugs. It also invades doctors' privacy and intrudes on the doctor-patient relationship."



representing the New England Journal of Medicine, the Vermont Medical Society, the Massachusetts Medical Society, the New Hampshire Medical Society, the National Physicians Alliance, and the American Medical Student Association.

Vermont Attorney General William Sorrell, who has the primary responsibility for defending state law, made a strong case for the Vermont data mining statute. Vermont's brief pointed out that ". . . a detailed evidentiary record shows that the problem of aggressive and intrusive, targeted marketing using prescriber-identifiable data is real. It causes unnecessary, expensive, and potentially risky over-prescription of new drugs. It also invades doctors' privacy and intrudes on the doctor-patient relationship."

Four states now have anti-data mining rules in place: Maine, New Hampshire, Vermont, and Massachusetts (by regulation). The Vermont case has been argued, but it may be many months before the decision is published. Other states shouldn't be deterred from adopting laws promoting evidence-based prescribing by restricting the marketing use of data-mined health records. With careful attention to insuring the legislative record includes the many studies about marketing practices and impacts on appropriate prescribing and legislation that is narrowly tailored to the problem, we believe these laws can and will be upheld by the courts. We are hopeful that, if we succeed in the Vermont case, these issues will be finally resolved and other states will not face costly and obstructionist litigation.

ENDOWMENT FOR HEALTH AWARDS PPC GRANT FOR KIDS AND PSYCH DRUGS: JUST SAY KNOW

THE NEW HAMPSHIRE-BASED ENDOWMENT FOR HEALTH HAS awarded a grant to PPC to further explore issues related to questionable prescribing of certain antipsychotic drugs to children.

Initial funding for PPC's *Kids and Psych Drugs: Just Say Know* initiative was supported by the Sadie and Harry Davis Foundation and the Maine Community Foundation. It enabled initial research to bring attention to the issue and highlight how states and the federal government are working to ensure safer and more effective prescribing of such drugs to kids.

The Endowment for Health grant will enable PPC to extend its research to better understand the extent of prescribing and use of antipsychotic drugs to kids participating in state health programs in New Hampshire. PPC will work with state policy makers and other stakeholders to identify best practices regarding the use of antipsychotic drugs in kids. The initiative will also include working with consumer and children's advocacy groups to gain an understanding of the issue, as well as potential risks associated with the drugs, and to empower parents and guardians to work with their doctors to make informed decisions about their children's mental health care.

An FDA advisory panel's recent recommendation that three antipsychotic drugs be approved for treatment in kids and adolescents is an example of why there is cause for great concern. The panel's recommendation was lukewarm at best, with one of the drugs, Ziprasidone, receiving only eight votes in favor of acceptable safety. One panel member voted it was not safe, while nine abstained from voting. Concerns about cardiovascular risk, including sudden death, were raised about the drug's use in kids. Risks associated with the other two antipsychotic drugs under consideration included substantial weight gain and metabolic problems, including increases in blood lipids and glucose, and certain movement disorders. Since the FDA usually follows recommendations made by its advisory panels, it appears approval is imminent.

If the lukewarm recommendation and associated risks of these drugs aren't enough to cause concern, the diagnoses for which the drugs are being recommended should be. While young patients with severe diagnoses including schizophrenia may benefit, the panel's recommendations includes possible use for patients with "mixed episodes associated with bipolar I disorder." Since the diagnosis is not as specific as schizophrenia, worries about more children being unnecessarily prescribed the powerful antipsychotic drug and being exposed to serious risks have been expressed.



PPC will work with state policy makers and other stakeholders to identify best practices regarding the use of antipsychotic drugs in kids.

Ziprasidone, for example, also marketed as Geodon, was front and center in the Justice Department's recent drug settlement with Pfizer. The drug company settled allegations it violated the federal False Claims Act by "knowingly causing false or fraudulent claims for the drug . . . by illegally promoting it for uses not approved by the FDA and that were not medically-accepted indications . . ." The company created and disseminated unsubstantiated and false information about the safety and efficacy of the drug and paid kickbacks to health care providers to induce them to prescribe it. While new panel recommendations include ensuring the FDA narrowly defines bipolar disorder on the label of the drug once it is approved for use in kids, it is no guarantee the drug won't be marketed by its maker more broadly. In fact, given the industry's history of marketing drugs for off-label purposes, and its disregard for the law and patient safety in general, we anticipate these drugs will be heavily marketed for broader use than intended. PPC's mission is to improve access to safe and effective medicine, and the Endowment for Health's grant to support *Kids and Psych Drugs: Just Say Know* is timely and important in addressing possible inappropriate prescribing of powerful antipsychotic drugs to kids.

For a version of this article with citations, please go to www.policychoices.org. To learn more about the Pfizer settlement, please go to www.stopmedicarefraud.gov/pfizerfactsheet.html.

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Promoting drugs for off-label use and offering monetary or other inducements to prescribers are common industry practices not limited to Pfizer. The constant flow of million-dollar, and now billion-dollar, settlements seem to indicate they are simply factored in as a cost of doing business. These examples highlight the need to focus on prescription drug policy as part of the larger health care reform debate. As an organization providing objective research, information and on-the-ground expertise on prescription drug policy, PPC is hard at work doing just that. We continue to promote policies we believe will help improve access to safe and affordable drugs in the US.

Promoting drugs for off-label use and offering monetary or other inducements to prescribers are common industry practices

This issue of *Perspectives* offers information on measures being taken to counter dubious drug industry sales strategies. The state of Vermont, for example, passed strong industry gift disclosure legislation this year, serving as a model for Congress which is contemplating similar legislation at the federal level. PPC's work to promote evidence-based prescriber education continues, as does our legal work to defend policy at the state level intended to protect prescriber information. For more information and tools to help policy makers and consumers make informed choices about prescription drug policy, feel free to visit www.policychoices.org.

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As Ken Liberto, director of the Vermont Association for Mental Health and supporter of the new law, told the *New York Times*, "If the drug industry gives \$3 million on average for three years now to physicians in a small state like Vermont, what is happening in California and New York?"

A flashpoint in the legislative debate was whether to require disclosure of free drug samples. In a compromise, the law required the Vermont Attorney General to hold a hearing and prepare a study to be submitted to the Legislature in December. The hearing was held in October with testimony on the question of disclosure. There was also testimony as to whether free samples are a good idea at all: Are they, as reported by the Associated Press, "a boon to doctors trying to provide medicines to low-income patients and those without insurance, or a marketing ploy that distorts the way health care is delivered?"

The hearing drew dozens of drug industry lobbyists opposing disclosure, including Marjorie Powell, counsel to PhRMA. Academics and health care advocates supported disclosure, and health care providers testified on both sides of the question.

The new Vermont law will collect important data on industry practices that will be useful to researchers and policymakers throughout the country. Its provisions will provide a road map to other states and the federal government moving ahead with transparency and gift legislation. All eyes will be on the Vermont Legislature in 2010 as it considers the Attorney General's report on sample disclosure and ponders whether to take further action on this emerging and contentious issue.

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Prescription Policy Choices

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LAWYERING FOR ACCESS LEGAL CONFERENCE

In October, PPC and the Program on Information Justice and Intellectual Property (PIJIP) cosponsored the legal conference, *Lawyering for Access: Legal Strategies to Improve Access to Affordable Pharmaceuticals*. The conference, which was held at American University Washington College of Law, included speakers who were involved in the Pfizer settlement and other significant health care cases. The session on Pharmaceutical Litigation: Safety, Pricing, and Promotion featured these panelists:



Michael Loucks, Acting US Attorney, District of Massachusetts, who was one of the lead attorneys in the Justice Department's recent landmark settlement with Pfizer, presented "US v Pharmacia & Upjohn Company, Inc—Prosecuting Pharmaceutical Fraud under Criminal and Civil Law."



Wells Wilkinson, Director, Prescription Access Litigation, spoke about "The Role of Private Litigation in Policing Pharma Practices." As director of Prescription Access Litigation, Wilkinson works to make prescription drug prices more affordable for consumers, using class action litigation and public education.



Allison Zieve, Director, Public Citizen Litigation Group, presented "Wyeth v. Levine—Preserving a State Right of Action in Pharmaceutical Litigation." Before the Supreme Court, Zieve argued the case involving musician Diana Levine, whose arm had to be amputated after an improper injection of Wyeth Pharmaceutical's drug, Phenergan. The Supreme Court ruled in Levine's favor.

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