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A NEW KIND OF HOUSE CALL DELIVERS SCIENCE NOT SALES

Prescription Drug Reform that Works

By Jennifer Reck

The Justice Department's recent $2.3 billion settlement with Pfizer achieved the dubious distinction of being the largest health care fraud settlement in its history.[1] Though unique in its size, this settlement isn't unique in its content. Promoting drugs for unapproved, unscientific use (off-label promotion), 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, seems to indicate they are simply factored in as a cost of doing business. Viewed together, they are a record of an industry that has put profits before patient safety and private gain before the public good.

Prescription drug sales reached $286.5 billion in the US in 2007, up from $40.3 billion in 1990. During the intervening years, the pharmaceutical industry reoriented itself from an R&D-focused venture to a marketing-focused venture.[2] In 2007, marketing expenditures totaled $10.4 billion with $6.7 billion of that directed at physicians.[3]

Public payers, including states like Maine, under pressure from rising health care costs, have turned a critical eye on pharmaceutical marketing, questioning its impact on patient care, health care quality and costs. The current wave of health care reform has raised the question of value, and both public and private payers are asking: Are we getting the best value for the billions we invest in prescription drugs? Are we spending our dollars rationally? Or simply as industry marketing dictates?

The pharmaceutical industry has long known that individual visits to a physician's office are an effective way to promote products, and accordingly has invested in a force of sales representatives totaling about 90,000 in number. These "sales reps" appear at the doorstep of a health care provider, often bringing lunch, branded gifts and office

Independent information about prescription drugs has been proven to improve quality and reduce costs.

supplies, and drug samples, to promote their company's newest, most expensive drug. Studies show that even small gifts can influence decision-making.[4] Industry sale representatives get paid on commission for promoting the use of their brand name drugs – regardless if there are safer, more time-tested, more affordable and clinically-effective options. It's not part of their job to objectively compare choices. Their job is to get their brand prescribed as much as possible.

A Better Alternative: Independent Information

In contrast to the industry "sales rep" approach, prescriber educators – or "academic detailers" – are not trying to sell anything. Academic detailers are trained clinicians, usually a physician, pharmacist, nurse or physician assistant. Their only "product" is independent, scientific information based on rigorous reviews of available data. This voluntary service is not an attempt to mandate, but to inform. The prescribing decision is always left to the professional judgment of the individual prescriber. Prescriber education is a useful tool for providing busy prescribers with the independent information they want to provide quality care. It's the information most of us want our doctors to use when we need care. Decades of peer-reviewed, published research has demonstrated that prescriber education and outreach – by empowering prescribers with the complete, unbiased information they need to choose the safest, most effective, and cost-effective drugs for their patients – can improve quality while reducing costs.[5] One pilot among Medicaid populations found savings as high as two dollars for every one dollar invested in the program.[6]

A recent report estimates that more than $58 billion may be wasted due to the inappropriate use (over-use and under-use) of prescription drugs each year,[7] representing approximately 20% of total annual prescription drug spending. For many classes of drugs, the chasm between the appropriate, evidence-based usage of a drug and the actual usage is immense.[8] Aggressive marketing of the newest, most profitable, patent-protected drugs, while safer, effective and less expensive alternatives are available, goes a long way to explaining this chasm. The pharmaceutical industry enjoys returns on investment as high as 10:1 for every dollar invested in these marketing efforts.[9] The commercial incentives to promote over-use or inappropriate use of the most expensive medicines are strong, and their influence is pervasive.

Policies to Curb Undue Industry Influence and Advance Evidence-Based Prescribing

Ensuring value in prescription drug spending requires a range of policy solutions. While there is no single magic bullet, a mix of policy options can help tip the balance from inappropriate or unnecessary use to evidence-based use. One set of policy responses seeks to limit undue influence from marketing by limiting or banning gifts to physicians (Massachusetts, Minnesota and Vermont) or by requiring the disclosure of such gifts over a certain dollar value (Maine and others). A related law in Maine, New Hampshire and Vermont restricts data-mining – the access and use of a physician's prescribing history for marketing purposes. At the state and federal level, there is also the need to invest in consumer protection enforcement to detect fraud which often takes the form of kick-backs and the promotion of drugs for off-label use.

A second, complementary set of policy responses is aimed at promoting evidence-based medicine. Scandals such as Merck's suppression of data indicating serious safety concerns relating to the pain-killer Vioxx have precipitated legislation, first in Maine and then at the federal level. Maine's law requires pharmaceutical companies to register the existence and intent of a clinical trial before it commences, and results when it is completed, in order to prevent the suppression of commercially unfavorable results.

In addition to making sure all industry-funded research sees the light of day, the federal government has recently invested $1.1 billion dollars in comparative effectiveness research (CER) as part of the American Recovery and Reinvestment Act (ARRA) of 2009. This research answers important questions about relative differences in efficacy, safety and value of certain treatments. It provides vital information to help doctors and patients choose treatments and prescription drugs clinically proven to outperform other options. It's information about what works, is safest and most effective; it's information most consumers want and assume is being used when they receive care. The ARRA identified

Prescriber education programs are part of a continuum of policies intended to ensure safe, effective, high-quality, high-value care related to prescription drugs

CURBING UNDUE OR ILLEGAL MARKETING PRACTICES:

- Disclosure or prohibition of gifts and payments to prescribers
- Prohibiting data-mining of prescribing histories for marketing purposes
- Consumer protection enforcement

PROMOTING EVIDENCE-BASED MEDICINE:

- Clinical trial registries to guarantee negative findings are not suppressed
- Comparative effectiveness research
- Prescriber education and outreach / academic detailing programs

effective dissemination of CER findings as a priority. Prescriber education provides this vital link by bringing the best, most up-to-date, independent scientific findings of CER or other research, into a practitioner's own office.

Prescriber Education Programs

Prescriber education is not reducible to generic substitution. Likewise, it considers costs only to the extent that cost-savings can be achieved without any compromise to safety and efficacy. For example, in some cases, if the research demonstrates that a newer, more expensive drug is indicated for a group of patients (such as the antiplatelet Plavix), it may indeed recommend the drug for that specific group. In cases where expensive brand name drugs (such as the heartburn drug Nexium) offer no practical advantage over lower-priced generics, the generic may be suggested as a logical choice. In sum, it is a quality-driven service with a premium on achieving optimal patient outcomes.

Prescriber education programs have successfully operated on a large scale for more than a decade outside the US in countries such as Canada and Australia. Within the US, the momentum behind these programs has gained considerable speed over the past five years. The concept of academic detailing was developed and researched for decades by Dr. Jerry Avorn of Harvard Medical School / Brigham and Women's Hospital and others. Avorn's nonprofit Independent Drug Information Service (iDiS) has overseen prescriber education for the state of Pennsylvania's elderly drug assistance program since 2005. The program has demonstrated success at improving prescribing practices and controlling costs relating to drugs commonly used for the treatment of heartburn and for managing cholesterol. Other common drugs that have been the focus of academic detailing in Pennsylvania or elsewhere include those for the treatment of pain, depressions, insomnia, and hypertension among others.

In 2007, Maine passed legislation authorizing the state to create a prescriber education service. Vermont passed legislation that same year tripling funding for its existing program in response to its success and requests for visits. In 2008, New Hampshire passed enabling legislation supporting the development of an academic detailing program there.

In response to the interest in evidenced-based prescriber education programs in the Northeast, Prescription Policy Choices (PPC), a Maine-based nonprofit, educational public policy organization dedicated to increasing access to safe, effective and affordable medicine in the US, launched its Academic Detailing Planning Initiative.[10] PPC brought policy makers, physicians and health advocates from the Northern New England states together, along with representatives from existing programs in Pennsylvania, South Carolina, Canada and Australia for an "Academic Detailing Summit" to identify best practices and to explore opportunities for collaboration. The summit and follow up meetings resulted in a white paper on developing and implementing prescriber education programs, opportunities for collaboration and funding sources (available at www.policychoices.org).[11]

Momentum continues with new programs being launched in Maine, the District of Columbia, Massachusetts, New York as well as a pilot in Idaho and another in Oregon. Pending legislation is currently under consideration in California, Minnesota and Wisconsin. A federal bill, known as the Independent Drug Education and Outreach Act (IDEA, H.R. 1859 and S.767), would create a two-pronged federal grant program for the creation of educational materials to be used in prescriber education as well as for the actual dissemination of those materials through academic detailing office visits.

Despite their ultimate potential to improve care and create savings, prescriber education programs do require a commitment of resources to get off the ground. While this can be a challenge in the current economic climate, some states have recently expanded or established effective programs with minimal resources. Existing funding models include manufacturer fees, pharmaceutical settlement funds, Medicaid match and federal grants (Agency for Health Care Quality and Research). Collaborative models have also been actively pursued. New England states including Maine, New Hampshire, and Vermont have worked together in an attempt to share knowledge and to find ways to make scarce resources go further. For example, many states, including Maine, get their educational materials from iDiS, which is evolving as a center for credible, independent, highly-rigorous scientific reviews and educational materials. This saves the time and expense of having multiple states investing in the creation of educational materials on the same clinical topics.

Maine's Prescriber Education Program

The Maine Independent Clinical Information Service (MiCiS) was launched in August of 2009. It is a free, voluntary educational service for Maine prescribers 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.

Academic detailers Erika Pierce, PA-C (left), and Noel Genova, PA-C (right), with Noah Nesin, MD, Maine Academic Detailing Advisory Committee chair-person.

The program employs two part-time academic detailers who are both physician assistants with clinical experience who have completed training in academic detailing conducted by iDiS in Boston. The 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. Further information is available online at www.mainemed.com/academic/index.php.

Engaging Consumers

While academic detailing reaches out to prescribers, consumers also play an important role in health care decision-making. The pharmaceutical industry spent $3.7 billion on direct-to-consumer advertising in 2007,[12] reaching consumers with an average of 80 drug ads every hour, every day.[13] In the face of this non-stop advertising, consumers are in need of balanced, consumer-friendly information sources. To that end, Prescription Policy Choices, through a grant from the Maine Health Access Foundation, is working to develop a consumer component into Maine's prescriber education program. PPC has also partnered with Consumers Union and *Consumer Reports Health Best Buy Drugs*™ (www.crbestbuydrugs.org) to provide consumers with unbiased information about drugs available to treat specific illnesses and diseases, differences among them and how they stack up against each other. Consumer preference can play an important role in prescribing decisions, and *Consumer Reports Health Best Buy Drugs*™ helps to offset the aggressive direct-to-consumer advertising conducted by drug companies. With the right tools and easy to understand information, consumers can learn to self-advocate for the safest, more effective drugs at the best price.

About the Author

Jennifer Reck, MA is a policy analyst for Prescription Policy Choices, Hallowell Maine. Prescription Policy Choices is a nonprofit, public policy organization dedicated to expanding access to safe, effective, and affordable prescription drugs. Information on academic detailing and other prescription drug-related policy issues are available at www.policychoices.org. The author acknowledges and appreciates editing contributions provided by Ann Woloson, Executive Director, Prescription Policy Choices

Endnotes

1 A fact sheet on this settlement is available at www.stopmedicarefraud.gov/pfizerfactsheet.html. Maine's share of the settlement was $1 million.
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10 The Academic Detailing Planning Initiative was generously funded by the Nathan Cummings Foundation, the Endowment for Health, the Maine Health Access Fund and the Bingham Project.
11 Reck, J. A template for establishing and administering prescriber support and education programs: A collaborative, service-based approach for achieving maximum impact, Prescription Policy Choices, July 2008.
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