

States in the Vanguard: State Initiatives Promoting Evidence-Based Prescribing & Regulating Drug Marketing

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N L A Rx

National Legislative Association
on Prescription Drug Prices

What is NLARx?

- State legislators working together across state lines to reduce drug costs and expand access to medicines since 2000
- Funded by states and grants not pharma
- Legislators from Hawaii to Maine
- Check out our website and biweekly newsletter: www.reducedrugprices.org
- Technical assistance, conferences, model legislation, amicus participation in relevant cases

Why do we care?

- Public health
- Preserving doctor-patient relationship
- Health care costs
- Health care access

State policies addressing drug marketing – context for action

- Reporting on gifts, marketing & advertising
- Gift bans
- Regulating misleading marketing tactics and setting standards for drug detailers
- Restricting data mining of prescriber information for marketing purposes
- Regulating e-prescribing software marketing & privacy
- Posting clinical trials data
- Prescriber education (“academic detailing”)

Marketing Disclosure: Initial focus on drug prices

- Pharmaceutical costs out of control
- Consumers, government and other payers can't afford drugs
- Clearest linkage in WV law: “find out what's spent on marketing & deduct from reference price”
- Interest in VT, ME in exposing \$\$ spent on marketing rather than R&D to support efforts to require discounts in MaineRx, Vermont program

Newer focus on medical care, preventing conflicts of interest

Data and media reports have had powerful impact on legislators, public... *concerns about*

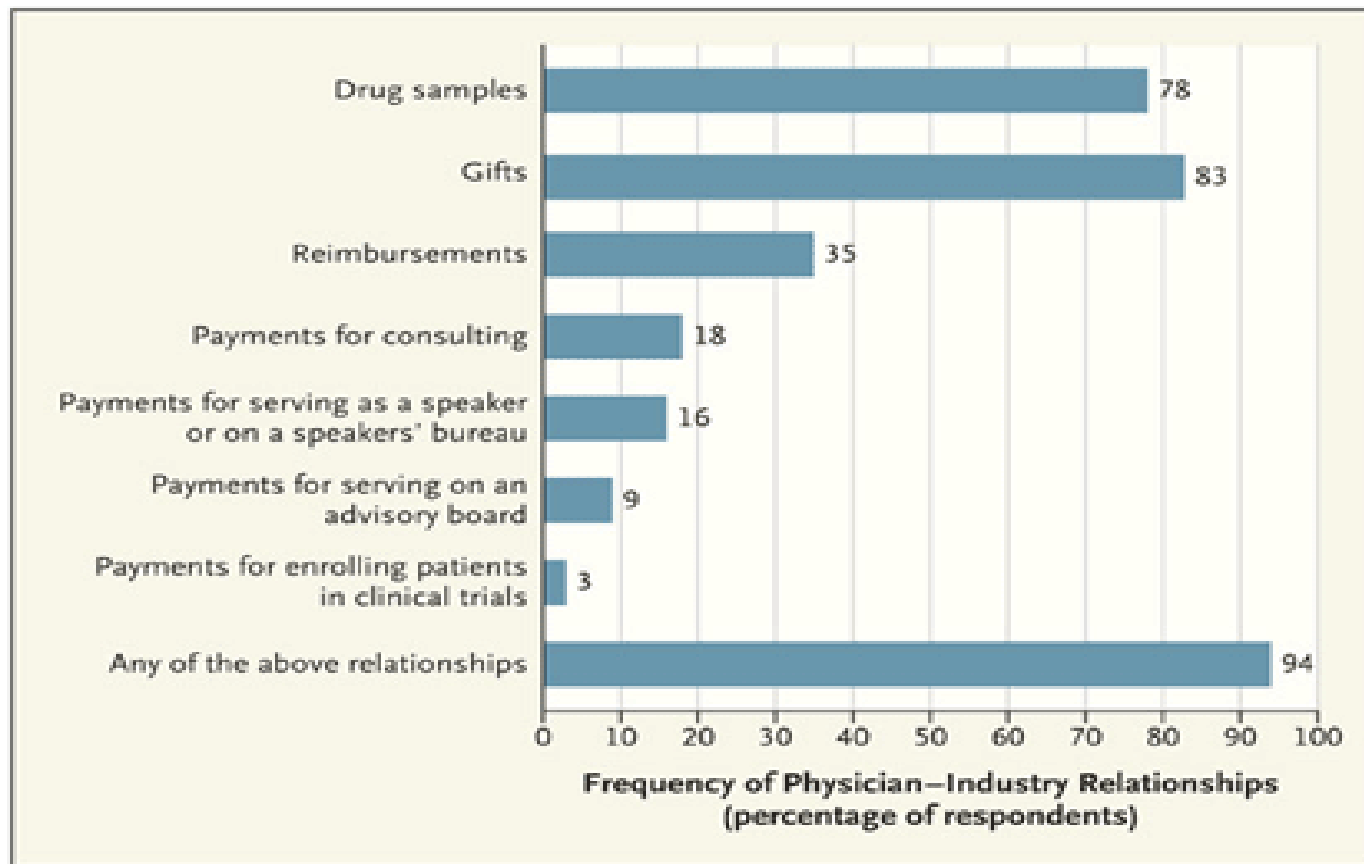
- Out of control industry marketing
- Industry influence in medicine
- Industry influence in government
- Quality of care compromised

A recent study published in the New England Journal of Medicine indicates that 94% of physicians have received food, drug samples or other payments or reimbursements from the industry.

Campbell, E.G. et al., NEJM, “A National Survey of Physician-Industry Relationships,” 4/26/07, 356(17):1742-1750.



Campbell and Campbell et al, NEJM: 2007



“The current influence of market incentives in the United States is posing extraordinary challenges to the principles of medical professionalism.”

Brenna, Rothman, Blank, et al., *JAMA*, “Health Industry Practices that Create Conflicts of Interest,” Vol. 295, No. 4, 1/25/06, pg 430.

Institute Of Medicine Report

- **According to a 2009 report from the Institute of Medicine of the National Academies:**
 - Acceptance of meals and gifts and other relationships create a real and perceived conflict of interest between physicians and pharmaceutical, medical device, and biotechnology companies.
 - These relationships may influence physicians to prescribe a company's medicines even when evidence indicates another drug would be more beneficial to the patient. <http://www.iom.edu/CMS/3740/47464/65721.aspx>

The Public Wants to Know

- June 2008 Pew Prescription Project survey found a majority of Americans (64%) want to know about their physicians' financial ties to pharmaceutical companies
- 68% of the public would support legislation requiring disclosure
- Most Americans disapprove of even small gifts to physicians

“The Nightmare’s Coming True”



Minnesota Got Things Started

151.461 GIFTS TO PRACTITIONERS PROHIBITED.

It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section

1993



Attorney General Skip Humphrey

Minnesota Rx Gift Reporting

- MN has had a gift ban in place since 1993, but it has many exceptions.
- MN began collecting data on gifts on January 1, 2002.
- Pharmacy Board only receives the data and does not report it to the public.
- MN was only state to require physician's name; now joined by MA and VT.
- Pending federal legislation (PPSA)

Gift reporting and bans

- Enacted laws:
 - MN (reporting/ban)
 - MA (reporting/ban)
 - VT (reporting/ban)
 - ME (reporting; ban pending)
 - D.C. (reporting/limited ban P/T)
 - WV (reporting)

Pending legislation

- Annually since 2007 about a dozen states have had bills for marketing disclosure
- In 2009 new or enhanced gift ban and/or disclosure legislation was considered in 19 states (AZ, CO, CT, DC, IA, IL, ME, MD, MI, MN, NM, NV, NY, OH, OR, RI, TX, VT, and WV).

Reporting on Marketing

Reporting by Manufacturer or Labeler:

- Date of Payment/Gift
- Recipient
- Value
- Type of payment (e.g., book, cash or check, donation, food, grant, lodging, transportation, samples)
- Purpose (e.g., consulting, professional education, charitable grant, speaker fee or payment)

Minnesota Data

- First 3 years' of data was photocopied and analyzed by researchers for a 2007 article in JAMA.
- For 2002-04 MN payments were \$30.9 million
- Amgen made over \$4 million in payments in one year.

Minnesota (cont'd)

- Eight companies made over \$1 million in payments 2002-04
- GlaxoSmithKline paid \$5.8 million 2002-04
- Top speaking fees was \$154,188 for one physician in one year
- Top research payment was \$922,239 for one physician in one year
- Calendar year 2007 manufacturer reports now on the web as received, still not user friendly.

2007 series of articles focused attention on Minnesota data

The New York Times

by GARDINER HARRIS:

“Doctors’ Ties to Drug Makers Are Put on Close View” - March 21

“Psychiatrists, Children and Drug Industry’s Role”
– May 10

“After Sanctions, Doctors Get Drug Company Pay”
– June 3

“Minnesota Limit on Gifts to Doctors May Catch On”
- October 12

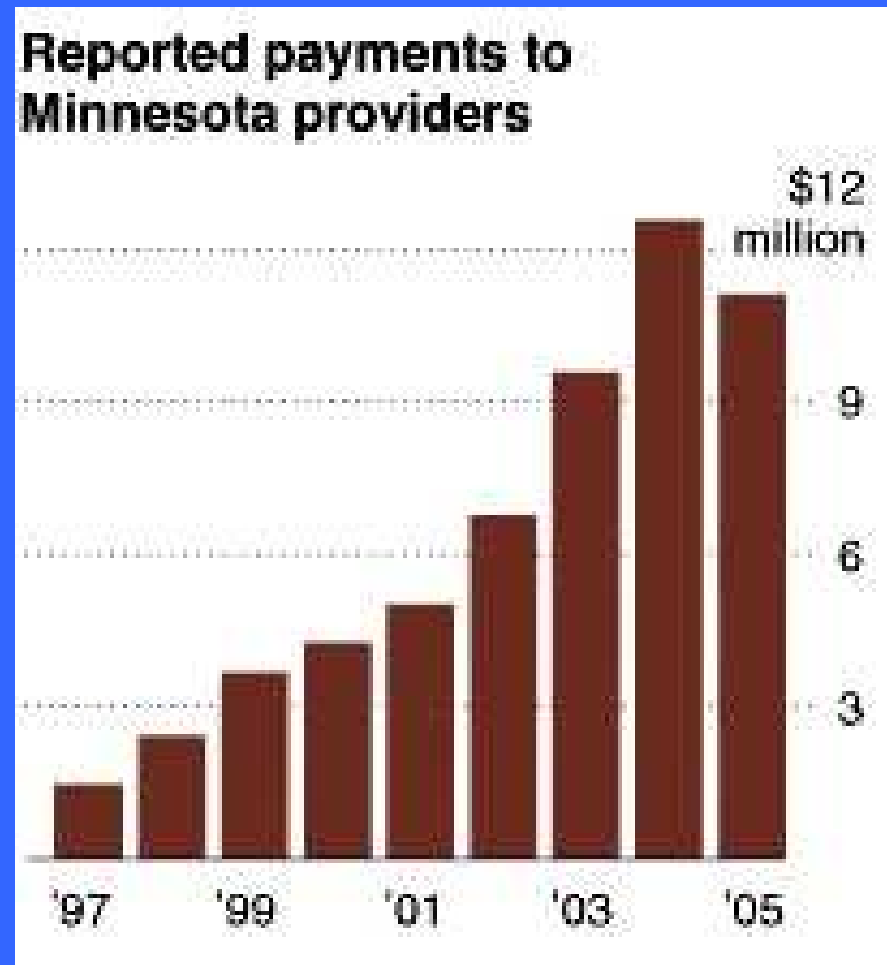
Minnesota Board of Pharmacy

National Attention to MN Gifting Law- 2007

The New York Times

Gardiner Harris – March 21, 2007

- **Health Care Providers in Minnesota received at least \$57 million from Drug Companies from 1997 to 2005**
- **25 % reported**



Minnesota Board of Pharmacy

National Attention to MN Gifting Law- 2007



The New York Times by Gardiner Harris – May 10 ,2007

Psychiatrists, Children and Drug Industry's Role



Sharon Treat, NLARx – December 16, 2009

Average number of prescriptions for atypical antipsychotics for children written by Minnesota psychiatrists who received the following amounts of money from the drug makers from 2000 to 2005:

PAYMENTS	PRESCRIPTIONS*
\$5,000 or more	223 
Under \$5,000	67 

* For children enrolled in Minnesota's fee-for-service Medicaid program

Sources: Minnesota Board of Pharmacy; Minnesota Medicaid

Recent MN Data

- The Pew Prescription Project analysis of MN data: Forest Laboratories Inc. paid 62 MN doctors at least \$1,000 each in speakers' fees; 28 received payments of more than \$10,000
- Forest paid MN practitioners more than \$750,000 in 2008

Payments linked to marketing

- 32% of these payments went to psychiatrists and neurologists, frequent prescribers of antidepressants.
- A report released by congressional investigators highlighted how Forest marketed Lexapro, a depression drug that reaped \$2.3 billion for the New York-based company last year.

Vermont Rx Gift Reporting

- 2007 JAMA article also analyzed VT data
- In 2007, \$3.1 million total payments; 33% increase over 2006
- Psychiatrists in top 100 group averaged almost \$57,000 apiece
- Two top VT cardiovascular docs' avg. payment was \$156,440 in 2007
- Cash payments exceed meals and trinkets

Vermont data 2008

- Only 17% of information publicly available (trade secret provision in prior law)
- Total 2008 Payments: \$2.9 Million
 - \$2.1 million total to MDs
 - 2280 recipients
 - 4573 total licensed health care professionals

Vermont Act 59 Disclosure & Gift Ban Requirements (2009)

- Includes manufacturers of prescription drugs, biological products, and medical devices
- Bans most gifts of any value, including food
- Requires disclosure of allowable expenditures and *permitted* gifts to health care providers
- Requires disclosure of allowable expenditures and *all* gifts to academic institutions and professional, educational, or patient organizations representing or serving health care providers or consumers
- Reports to the attorney general annually
 - October 1

Act 59: Exceptions to Gift Ban

- Samples & Labels
- Short-term loan of a 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
- Rebates and discounts provided in the normal course of business

Act 59: Disclosure Exceptions

- Royalties and licensing fees
- Rebates and discounts
- Samples of prescription drugs – hearing in October 2009 on whether to require disclosure

Act 59: Clinical Trials Disclosure

- Delayed reporting of payments for clinical trials
- Full information after the earlier of the date of:
 - the approval or clearance of the prescribed product by the Food and Drug Administration or
 - two calendar years after the date the payment was made.
- Immediate reporting of the name of the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry (www.clinicaltrials.gov)

Rx Gift and Payment Reporting – Ongoing Issues

- Ban vs. Reporting
- Aggregate vs. individualized
- “Research” payments (MA debate)
- Trade secrets loophole (VT lawsuit)
- Standardized electronic reports
- Public access – posting on the web
- Free samples
- Continuing Medical Education (CME)

Post Disclosure: Regulating Misleading Ads & Marketing Activities

- In 2005 Maine adopted FDA standards enforceable under Unfair Trade Practices Act - applies to DTC but not marketing to doctors
- AGs already enforce off-label marketing etc
- Vermont enacted 2007 law regulating detailer actions and marketing generally
- D.C. first to pass detailer licensing in 2008, also has off-label marketing provisions
- 2007 Nevada law will enforce detailer code of ethics
- 2009 Maine law regulates “predatory marketing” to children (in litigation)

Regulating Data Mining of Prescriber Records

- 2006 New Hampshire ban on “commercial use” defined as marketing use
- Vermont “opt in” and Maine “opt out” in 2007
- Pending in over a dozen states in 2009
- NH law upheld by 1st Circuit Court of Appeals (US Supreme Ct denied cert); VT law upheld and on appeal to 2nd Circuit; ME law initially enjoined, on appeal

What is “marketing?”

- Advertising, promoting, selling Rx drug
- Activities to influence market share or prescribing patterns
- Activities to evaluate or improve effectiveness of sales force
- Brochures, media ads, free samples
- Differs from AMA program which still allows use for marketing

What *isn't* “marketing?”

- Pharmacy reimbursement
- Formulary compliance
- Utilization review
- Health care research

E-Prescribing Software

- Maine PL 2007, Ch.362, “An Act to Prohibit the Sale or Distribution of Software that Contains Inappropriate Advertising of Prescription Drugs“
- Effective 1/8/08
- Modeled on 2006 Florida law, VT & NH also enacted in 2007

Pop-up Ads Verboten

- Software can't "influence or attempt to influence" a prescribing decision or direct patient to certain pharmacy
- Law bans pop-up ads, instant messaging, economic incentives triggered by selection or act of prescriber

Australia Experience

- 2005 study: advertising insinuated throughout e-prescribing software “Medical Doctor” (has dominant share of marketplace)
- Ads showed up in 24 different clinical functions from program installation to recording patient blood pressure, pain assessment, care plan & selecting drugs for prescribing

Academic Detailing

- PA program national leader
- Comprehensive evidence-based information, not just info on particular company's drug
- ME, NH & VT initiative with Prescription Policy Choices
- DC program up & running
- Federal ARRA and AHRQ interest

Posting Clinical Trials Data (Maine)

- Effective 2005
- Adverse information, why trials stopped
- Internet posting required
- Public education program funded (merged with academic detailing)
- Federal law enacted 2007 is similar and will preempt when it goes into effect

Regulating Misleading Ads

- Adopted FDA standards October 15, 2005
- Applies to advertisements but not other marketing activities (such as to doctors) although Attorney General already enforces off-label marketing etc
- VT enacted in 2007 plus regulates detailer actions and marketing generally; NV has detailer code of ethics

Marketing to Kids

Minors Targeted via Internet and MySpace



- Industry lures visitors, offering free gifts, samples, coupons, etc, in exchange for personal information
- Info. is unknowingly used to market products, and shared/sold to other marketers.
- Young children, under age 13 are provided some protections under COPPA (Children's Online Privacy Protection Act), but young teens and older children remain at risk.

Unintentional Consequences:

- Personal or health care related information collected, stored, shared, and used over time for marketing purposes (unknowingly)
- Children steered toward unnecessary drugs, or drugs which are more expensive, no more effective and sometimes less safe than other products on the market
- Identity theft – FTC warns against responding to pop-up ads and providing personal info. over internet

Maine Public Law 2009, Chapter 230

An Act to Prevent Predatory Marketing of Minors

- Bans the unlawful collection and use of health related or personal information for marketing purposes from minors without first obtaining parental (or guardian) consent
- Violations considered unfair trade practices – Attorney General may establish procedures for receiving and investigating complains of violations
- Provides Civil penalties for Civil violations and federal law application (Children’s Online Privacy Protection Act of 1998)

“There’s a New Sheriff on the Block!”



Some resources

- West Virginia reporting rule and first report:
<http://www.pharmacycouncil.wv.gov/rule/Pages/default.aspx>
- Most recent Vermont disclosure data:
http://www.atg.state.vt.us/upload/1215547635_2008_Pharmaceutical_Marketing_Disclosures_Report.pdf
- Summary of DC Reporting Data, initial report:
http://www.davidcatania.com/publicdocuments/Pharm_Marketing_Rpt_06.pdf
- Public Citizen Testimony on State Disclosure Laws before the Senate Special Committee on Aging, June 27, 2007:
<http://www.citizen.org/publications/release.cfm?ID=7531>

NLARx RESOURCES:

- Sign up for news releases and electronic newsletters:

<http://www.reducedrugprices.org/>

- Advertising & marketing web page:

<http://www.reducedrugprices.org/advertising.asp>

- Report on 2008 state legislation relating to marketing:

<http://www.reducedrugprices.org/read.asp?news=2669>

PRESCRIPTION PROJECT:

- State Policies:

<http://www.prescriptionproject.org/solutions/rrf?id=0001>

NCSL RESOURCES:

- State Laws on Pharmaceutical Marketing and Promotion:

http://www.acponline.org/advocacy/state_policy/reports/pharm_market.htm

- 2008 Rx legislation:

<http://www.ncsl.org/programs/health/drugbill08.htm>

- Advertising & marketing overview:

<http://www.ncsl.org/programs/health/rxads.htm>

More Info

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