New Sheriff on the Block

State Prescription Drug Marketing Disclosure Laws

Rep. Sharon Treat (Maine)
Executive Director,
National Legislative Association on Prescription Drug Prices

March 6, 2009
First Annual Summit on Disclosure
Washington, D.C.
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
- Partnering with The Prescription Project/Community Catalyst on payment & gift disclosure issues
State policies addressing drug marketing

- 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”)
Why do we care?

- Public health
- Preserving doctor-patient relationship
- Health care costs
- Health care access
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, conflicts of interest

Minnesota data has 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.

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

Gift reporting and bans

- Approximately a dozen states have had bills each year since 2007
- New or enhanced gift ban and disclosure legislation is under consideration this year in CA, CO, CT, DC, IA, IL, ME, MN, NM, NV, NY (in Governor’s budget), TX, VT, WI and WV.
- Enacted laws in MN (reporting/ban), VT (reporting), ME (reporting), D.C. (reporting/limited ban), WV (reporting), MA (reporting/ban)
"The Nightmare’s Coming True"

States Won’t Wait for Feds
The nightmare’s coming true—state mandates for costs disclosure are real.

Bills Pending in State Legislatures

Sharon Treat, NLARx - March 6, 2009
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)
Gift Reporting Continued

- Public reporting aggregates data except in Minnesota, where prescribers receiving gifts are individually listed in public data
- Vermont has 5 years of data on AG website
- Reporting also on advertising & marketing spending (including DTC) in most state laws
- Massachusetts only law to include medical devices
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 only state to require physician’s name.
Minnesota (cont’d)

- 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
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


Psychiatrists, Children and Drug Industry’s Role

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:

<table>
<thead>
<tr>
<th>PAYMENTS</th>
<th>PRESCRIPTIONS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>$5,000 or more</td>
<td>223</td>
</tr>
<tr>
<td>Under $5,000</td>
<td>67</td>
</tr>
</tbody>
</table>

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

Sources: Minnesota Board of Pharmacy; Minnesota Medicaid

Sharon Treat, NLARx - March 6, 2009

Slide Courtesy Pete Wyckoff, The Prescription Project
Vermont Rx Gift Reporting

- VT began collecting data on July 1, 2002
- First of five annual reports issued by the VT Attorney General on Feb. 25, 2004
- Most comprehensive reporting and analysis of any state, but individual physicians are not named.
- Gift ban and enhanced disclosure including public reporting of disaggregated data under consideration (S48).
Vermont (cont’d)

- 2007 JAMA article also analyzed VT data
- In most recent year (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 (cont’d)

- Exclusion for “trade secrets” is problem
- Used by 30 out of 68 companies
- 61% of total payments were excluded as “trade secrets” in first two years
- Information not entitled to trade secret status under usual standards
- Public policy favors disclosure
Maine Disclosure Law

- Law enacted in 2004
- Implementation delayed until 2007 with govt & PhRMA support
- Broad non-compliance: 116 companies did not file reports (or explain why not) in 2007; 96 did
- Annual reports of data by DHHS starting 2007 with biannual analysis starting 2008
- No reports publicly posted
- Only state law to require reporting and public disclosure of clinical trials results data
Maine Data

- Total direct to consumer advertising & marketing expenditures reported 2007: $1.6 million
- 1440 health care professionals received cash for travel, speaking, materials at lectures
- Top recipient received $118,540
- Of $1.271,921 reported as “education” spending, $982,786 was for speaker fees
- Food & gifts: $1.3 M
- Product samples: $7.3 M
- Salaries of drug reps and other marketers: $63 M
D.C. Rx Gift Reporting

- Reporting requirement effective January 1, 2006
- First detailed analysis released April 30, 2008
- Report includes advertising, marketing and aggregate expenditures
- 101 companies reported $145.5 million
District of Columbia (cont’d)

- Individual companies not named in report
- Apparent variability in the interpretation of the reporting requirements makes comparisons difficult
- 20 companies paid out over $1 million each
- Total Advertising = $10.8 million
- Total Marketing = $34.4 million
- Total “Aggregate” = $100.1 million
D.C. (cont’d)

- 2008 D.C. law also enacted a limited gift ban applicable to gifts to “medication advisory committees”
West Virginia Rx Gift Reporting

- First report issued July 7, 2008
- Only information reported is the total number of prescribers receiving > $100
- No enforcement mechanism
- First report showed 14,933 gifts and payments
- Governor announced support of enhanced disclosure to close loopholes
Massachusetts Law

- Requires drug and medical device companies to disclose payments to health care providers >$50
- Establishes a prescriber education program
- Gives Dept of Public Health power to establish regulations at least as strong as PhRMA Code which prohibits small gifts, travel payments, & extravagant restaurant meals to doctors
- Includes enforcement mechanism, penalties
- Flashpoint: Disclosure of Research Payments???
Update on Status of Pending Legislation

- New or enhanced gift ban and disclosure legislation is under consideration this year in CA, CO, CT, DC, IA, IL, ME, MN, NM, NV, NY (in Governor’s budget), TX, VT, WI and WV.
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 2007 14 states had bills to regulate misleading marketing
- 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
“There’s a New Sheriff on the Block!”

New Sheriffs on the Block: Growing Number of State Laws Target Drug Marketing and Promotion
Some resources

- West Virginia reporting rule and first report: [http://www.pharmacycouncil.wv.gov/rule/Pages/default.aspx](http://www.pharmacycouncil.wv.gov/rule/Pages/default.aspx)


- Summary of DC Reporting Data, initial report: [http://www.davidcatania.com/publicdocuments/Pharm_Marketing_Rpt_06.pdf](http://www.davidcatania.com/publicdocuments/Pharm_Marketing_Rpt_06.pdf)

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

Rep. Sharon Anglin Treat (Maine District 79)
Executive Director,
National Legislative Association on Prescription Drug Prices

P.O. Box 492
Hallowell, Maine 04347
Tel: 207-622-5597

Email: streat@reducedrugprices.org
Website: www.reducedrugprices.org