National Legislative Association on Prescription Drug Prices

Think Globally, Act Locally

State & local initiatives push national action

Sharon Anglin Treat

National Legislative Association on Prescription Drug Prices

Selling Sickness Conference

Washington, D.C.

February 22,2013

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WHO ARE WE?

- State legislators from Hawaii to Maine working together to reduce drug costs and expand access to quality medicines since 2000, taking a leadership role on marketing, conflict of interest and prescribing issues
- Funded by states and grants not Big Pharma
- Technical assistance, conferences, model legislation, amicus participation in relevant cases

Check out our website and e-newsletter:
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Health Care Role of States

Implementing & paying for Medicaid in partnership with federal government

- Preferred drug lists, drug rebate negotiation, prescribing oversight & education

State-based public health and health access programs

- Drugs for the elderly
- Vaccinations, HIV/AIDS, public health programs
- School-based health care

Providing health care for people in state care

- Corrections
- Foster children

Implementing policies & programs under Affordable Care Act

- Health benefits exchanges
- Essential benefits
- Electronic records & prescription databases

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Sources of State Policy

- **Litigation** by State Attorneys General has addressed misleading and deceptive marketing of drugs, clinical trials & safety issues
- **Statutes** enacted by state legislators have addressed many marketing and conflict of interest issues, safe prescribing, & privacy
- **Agency regulations** and DUR and PDL committees have addressed issues of prescribing safety, prescriber education

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Laboratories of Democracy: States Out in Front

- **First to require disclosure of advertising & marketing spending (Minnesota)**
- **First to ban gifts to doctors (Minnesota)**
- **First to require registration of clinical trials and posting of clinical trials data, including bad results (New York)**
- **First to require reporting of samples (Vermont)**
- **First to ban consumer coupons (Massachusetts)**
- **First to create comprehensive academic detailing, prescriber education programs (Pennsylvania)**

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Laboratories continued…

- **First to regulate conflicts of interest in prescribing software (Florida)**
- **First to regulate online marketing of drugs to children (Maine)**
- **First to address overprescribing of psychiatric drugs to children**
- **First to protect privacy of patient medical records, some of which go beyond federal law (Texas)**
- **First to protect privacy of prescriber prescription data (New Hampshire)**
- **First to regulate PBMs (Maine, Vermont)**
- **First to tackle the implications of trade policy on pharmaceutical marketing (Maine, Vermont)**

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Clinical Trials Data, Trials Posting

- **New York: 2004 litigation settlement required website posting of clinical trials after negative trial results withheld**
- **Maine law effective 2005 - more comprehensive than subsequent federal law**
  - **Must include info on adverse information, why trials stopped, aliases**
  - **Internet posting required**
  - **Public education program funded**
- **Federal law enacted 2007 is similar and included preemption of state laws when it went into effect**
- **2009 Vermont payment disclosure law required clinical trial reporting, payments data**

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Gift Bans & Reporting: Minnesota was First

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]

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State Gift Bans

MASSACHUSETTS (2008) - Comprehensive law bans most payments by drug & device companies but flashpoint is the meal ban – continuing efforts to repeal this section:

"The marketing code of conduct adopted by the department shall not allow: (1) the provision of or payment for meals for health care practitioners that: (a) are part of an entertainment or recreational event; (b) are offered without an informational presentation made by pharmaceutical marketing agent or without the pharmaceutical marketing agent being present; (c) are offered, consumed, or provided outside of the health care practitioner's office or hospital setting; or (d) are provided to a healthcare practitioner's spouse or other guest"

VERMONT (2009) - Bans gifts by manufacturers of prescription drugs, biological products, and medical devices to health care providers (anything of value provided to a health care provider for free, with exceptions). Most exceptions must be reported.

- Covers prescribers, office staff, hospitals & long-term care facilities
- Includes meals
- Free samples allowed but law amended to require disclosure of free samples of prescribed products, starting in 2012, including the product, recipient, number of units, and dosage. AG may contract with academic researchers for analysis and aggregated public reporting. Unlike other reporting, subject to confidentiality provisions; without names or license numbers of individual recipients

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"The Nightmare's Coming True"

PHARMACEUTICAL EXECUTIVE MARCH 2005 www.pharmexec.com

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States Won't Wait for Feds

The nightmare's coming true—state mandates for costs disclosure are real.

Bills Pending in State Legislatures

State	DATE INTRODUCED » Area of Impact
California	JANUARY 05 » Disclosure

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Federal Sunshine Law

- **Federal reporting law (Physician Payment Sunshine Act) enacted as part of the Affordable Care Act in 2010**
  - **17 years after Minnesota's law passed**
  - **CMS slow to implement – did not meet deadline in law, issued rules more than a year late**
- **Disaggregates data but scope less comprehensive than VT & MA laws**
- **Are states preempted?**
  - **Yes for: Duplicative reporting requirements, as of January 1, 2012**
  - **No for: Restrictions or prohibitions on transfers or gifts ("gift bans") or additional or different reporting requirements**

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Payment Disclosure Makes a Difference

The New York Times

Psychiatrists, Children and Drug Industry's Role
By Gardiner Harris (May 10, 2007)

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

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2012: Minnesota limits psych drugs for children

Star Tribune, June 5, 2012: "Doctors must consult Mayo service before prescribing psychotropics"

http://www.startribune.com/lifestyle/health/157096785.html

"Concerned by a sharp rise in the use of powerful psychiatric drugs for adolescents, Minnesota will start requiring doctors in many cases to begin using a state-funded consulting service before prescribing such medications for children."

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2012 DC Study:
Pharmaceutical Marketing
Focus on Use of Antipsychotics in Children

Antipsychotic manufacturers are marketing heavily to District psychiatrists, and appear to be targeting Medicaid psychiatrists in particular.

- **Of 172 District physicians receiving gifts totaling $1,000 or more from the top antipsychotic manufacturers, 26 (15%) were psychiatrists, receiving gifts or payments valued nearly $500,000 (approximately a quarter of the $1.9 million received by all 172 physicians)**
- **Of 119 District psychiatrists accepting Medicaid in 2012, 42 (35%) received gifts from the top antipsychotic manufacturers in 2010 – a decline from 2008, when 56 of them received such gifts.**
- **Between 2007 and 2010, the value of the average individual gift received by Medicaid psychiatrists from top antipsychotic manufacturers has increased by 41%, while the average total amount received by Medicaid psychiatrists has increased by 85% – suggesting that while fewer Medicaid psychiatrists are receiving gifts than in prior years, the psychiatrists who continue to receive gifts are receiving more-expensive gifts.**

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States Reviewing Prescribing of Psychiatric Drugs to Children

- **2010 JAMA article: Children covered by Medicaid are far more likely to be prescribed antipsychotic drugs than children covered by private insurance, and Medicaid-covered kids have a higher likelihood of being prescribed antipsychotics even if they have no psychotic symptoms**
- **2010 16-state Medicaid Director's report: Children in foster care (12.4 %) were prescribed AP medications at much higher rates than those not in foster care (1.4%)**
- **2011 GAO Report: Foster children on Medicaid in those states received prescriptions for psychotropic drugs at rates 2.7 to 4.5 times higher than did nonfoster children on Medicaid. The rates were higher for foster children in all age groups.**
- **Columbia University study found a doubling of the rate of prescribing antipsychotic drugs for privately insured 2- to 5-year-olds from 2000 to 2007. Only 40 received a proper mental health assessment, violating practice standards from the American Academy of Child and Adolescent Psychiatry**
- **Some of the states reviewing or establishing standards for prescribing to children, or where legislation introduced in past 2 years: Washington, Arkansas, Maine, Florida, Texas, Minnesota, Georgia, California, Nebraska, Colorado, Maryland, Nevada, Illinois, Connecticut, Oregon**

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Post-Disclosure: Regulating Misleading Ads & 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
- 2009 Maine law regulated "predatory marketing" to children (repealed after litigation)

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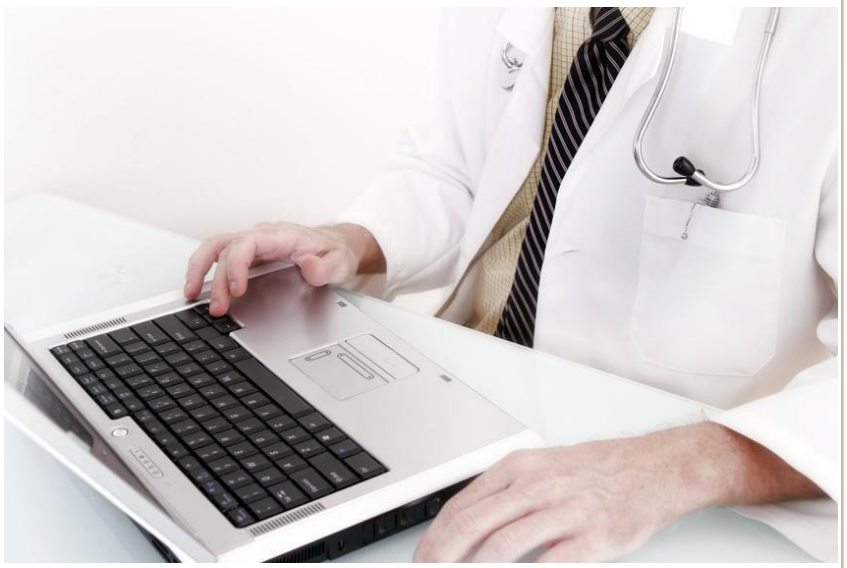
Australia's experience with prescribing software

- 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



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State Laws on Prescribing Software

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

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Regulating Misleading Ads & Marketing Activities

- Maine adopted FDA standards in 2005; applies to advertisements but not other marketing activities (such as to doctors)
- State Attorneys General already have broad authority to enforce off-label marketing
- Nevada has detailer code of ethics, and DC licenses pharmaceutical industry detailers

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Academic Detailing

- **Pennsylvania program national leader**
- **Comprehensive evidence-based information, not just information on particular company's drug. Addresses issues of safety, quality, and cost.**
- **Maine, New Hampshire & Vermont initiative with Prescription Policy Choices, medical societies & health foundations**
- **DC program up & running, programs in New York, Idaho, Massachusetts, Oregon, South Carolina**

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Social Media & Marketing to Children

Industry lures visitors, offering free gifts, samples, coupons, in exchange for personal information

Information is used to market products, and shared/sold to other marketers without knowledge or consent

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

Prescription Policy Choices
PO Box 204 Hallowell, Maine 04347 207.512.2138 fax: 207.622.3302 www.policychoices.org

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Free Trade Agreements: An End-Run Around Safety, Marketing & Pricing Regulations?

- Recent trade agreements (Korea-US, Australia-US, pending Trans-Pacific Partnership Agreement) seek to loosen rules for clinical trials and restrictions on marketing such as DTC advertising, and these treaties can override state & federal law.
- States paying attention:
  - Vermont Commission on International Trade and State Sovereignty
  - Maine Citizen Trade Policy Commission

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Ongoing role of the states

- **States have significant authority to act, unless barred by federal preemption or Constitutional constraints such as First Amendment (which also limit the federal government)**
- **State should act on all of the above because:**
  - **Federal government agonizingly slow to act – witness DTC ads, Internet marketing, social media regulations**
  - **States have a responsibility to protect children & those in their care – eg, foster children**
  - **States are responsible for Medicaid budgets and other drug spending, and implementing policies such as academic detailing help assure they spend on effective as well as cost-effective drugs, and NOT on deceptively marketed drugs or the newest blockbuster drugs that may be LESS effective than alternatives**
  - **States have a major role identifying problems and testing solutions, modeling policy alternatives for eventual federal action – eg, Sunshine Act**

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More Info

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