



A Ray of Sunshine

Review of Legislative & Regulatory Efforts to Increase Transparency of Physician-Industry Relationships

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Policy Context

- Collaboration w/physicians critical to industry & public
 - advances physician education
 - promotes optimal patient care
 - essential for R&D of new products
 - furthers scientific advancement
 - vital feedback & advice on products
- Marketing to physicians critical to industry
 - communicate directly w/patients
 - control access to drugs & devices (“gate-keepers”)



Industry Marketing Tools

Payment & gifts to physicians may include:

- free drug samples
- promotional items (logo-bearing pens, mugs, pads)
- educational items (anatomical models)
- free meals (restaurants, in-office)
- entertainment (tickets to events, sporting equipment, trips)
- continuing Medical Education (CME)
- third-party scientific & educational conferences, professional meetings
- consulting arrangements
- honoraria
- scholarships, research grants & educational funds



Spending on Physician Marketing

- Drug industry spent \$20.4 billion in drug marketing in 2007*
- \$6.7 billion spent on physicians (excluding Rx drug samples)
- Expenditures have declined in recent years^
 - \$7.8 billion in 2005
 - \$7.2 billion in 2006
- 94% of physicians reported a financial relationship with drug industry†

*Verispan: June 2008

^Kaiser Family Foundation, *Prescription Drug Trends*, May 2007 & September 2008

†E.G. Campbell et al., "Institutional Academic-Industry Relationships," *JAMA* 298, No. 15 (2007): 1779-1786; E.G. Campbell et al., "A National Survey of Physician-Industry Relationships," *New Eng. J. Med.* 356, No. 17 (2007): 1742-1750

Concerns

- Trust & cost control
- Potential for conflict of interest — may affect objectivity of
 - clinical research & data analysis
 - physician communications
 - treatment decisions
- Practices may drive-up spending
 - influence prescribing habits
 - Influence formularies & utilization management
 - increase overall prescription rates
 - reduce generic prescribing
 - increase prescribing of newer, more expensive drugs w/marginal safety & effectiveness
- Lack of transparency
 - “sunlight is said to be the best of disinfectants”



Self-Regulation

- PhRMA
 - Voluntary guidelines issued in 2002; revised 2009
 - Limits gifts & requires disclosure
 - ✓ limits meals to in-house/hospital setting w/educational presentation
 - ✓ bans most promotional items
 - ✓ no entertainment
 - ✓ no travel/payment for attending CME in absence of services provided
 - ✓ disclosure of marketing expenses, consultant agreements, speaker programs & CME sponsorship
 - 40+ PhRMA member & non-members have signed on
 - endorsed by HHS OIG
- AdvaMed adopted similar guidelines in 2003
- Companies
 - Eli Lilly, GSK, Merck & Pfizer now disclose gifts/payments to physicians
- AMA, ACP & many academic medical centers issued guidelines
- State & federal interest in regulation persists

State Activity

- States enacting “sunshine laws”
 - bans and/or restrictions on gifts & meals
 - require reporting of marketing expenses
 - require registration of marketing representatives
- States include
 - California
 - DC
 - Maine
 - Massachusetts
 - Minnesota
 - New Hampshire
 - Vermont
 - West Virginia
- Concerns
 - inconsistency
 - compliance
 - enforcement



Federal Enforcement Activity

- Increase OIG, DOJ & state enforcement actions
 - Range of pharma & device marketing practices
 - Criminal & civil
 - Qui tam investigations – 125 investigations involving 500+ drugs
- Allege violations of –
 - Federal & state anti-kickback statutes
 - False Claims Act
 - Ban on off-label promotion
- Examples
 - Pfizer: \$2.3B settlement for allegations it improperly marketed 13 drugs
 - Lilly: \$62M settlement for improper marketing of Zyprexa®
 - Cephalon: \$425M settlement for “off-label” promotion
- Increase in CIAs & DPAs
 - DPAs b/n DOJ & 4 device companies
 - DOJ alleged illegal inducements for docs
 - require disclosure of practices & govt supervision of agreements
 - device company ties to physicians much more entangled

Federal Legislative Activity

- Bashing pharma good PR for politicians
- Increased oversight of marketing practices
 - Hearings & investigations
 - House Energy & Commerce, Senate Finance & Special Aging Committees
- Legislative activity
 - Health care reform: increased scrutiny of health care industry
 - Trend towards greater transparency
 - Physician Sunshine Payment Act



Physician Sunshine Payment Act (S. 301)

- Sens Herb Kohl (D-WI) & Chuck Grassley (R-IA)
- First introduced in 2007 & revised in 2009
- Beginning April 2011, requires quarterly reporting of payments & gifts to physicians & disclosure of ownership interests
- Excludes
 - Payments less than \$100 per year (**NEW** – originally \$500)
 - Drug samples
 - Educational material for patient use
 - Anything below \$10 in value (**NEW** – originally \$25)
- Information must be posted online & made publicly available

Sunshine Act, cont'd

- Penalties for noncompliance
 - \$1K -\$10K CMP per violation, not to exceed \$150K per year
 - **NEW** – Originally \$5K max per violation & \$50K per year
 - “Knowing violations” – \$10K-100K CMP per violation, not to exceed \$1 million per year
 - **NEW** – Originally \$50K max per violation & \$250K per year
- **NEW** – HHS Secretary must submit to Congress each year a report of the information provided (aggregated by manufacturer) & any enforcement actions taken
- Limited preemption – states permitted to regulate information not addressed by Act



Industry Concerns

- Limited preemption could result in –
 - confusing patchwork of differing regulations
 - administratively cumbersome & expensive
 - smaller companies especially hit
 - different reporting requirements
 - different submission procedures/formats
- Disclosure requirements could –
 - chill essential interactions b/n industry & physicians
 - stifle interchange of ideas & information
 - reduce doc participation in clinical trials & CME
 - harm patient care



Outlook

- Transparency cornerstone issue of WH & Congress
- Addressed as part of current health reform debate
- Version of Sunshine Act included in –
 - Baucus' proposal, the *America's Health Future Act of 2009*
 - House E&C-passed health reform bill (H.R. 3200)
- House proposal –
 - requires reporting of significantly more entities than Senate version
 - less severe criminal & civil penalties
- Version of bill likely included in any health reform bill passed by Congress

