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## **State Ethics & Lobbying Laws for Pharmaceutical and Medical Device Companies**

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**8<sup>th</sup> Annual Pharmaceutical Regulatory Compliance Congress  
Washington, DC -- November 8, 2007**

# Overview

- Overview of State Political Laws
  - Awareness -- not a comprehensive overview of all laws/issues
- Key Issues and Potential “Triggering Events”
  - Lobbying
  - Ethics (Gifts / Entertainment, Hiring Public Officials)
  - Political Contributions\*
- Recent Developments
- Practical Issues and Strategies

# Overview of Political Laws

- What are “state political laws”?
  - Lobbying
    - Registration
    - Reporting, recordkeeping
    - Other restrictions
  - Ethics
    - Gifts, meals & entertainment
    - Hiring/compensating public officials

# Overview of Political Laws

- What are “state political laws” (cont.)?
  - Political contributions
    - Who can contribute, contribution limits
    - Reporting contributions
    - “Pay-to-play” statutes
    - Not a focus of today’s discussion
  - Others not addressed today:
    - Procurement laws
    - Fundraising / use of corporate resources / volunteering
    - Post-employment restrictions
    - Regulation of State PACs

# *Overview of Political Laws*

- Why care about compliance with state political laws?
  - Aggressive State Enforcement Officials
  - Violations Can Be Civil / Criminal Offenses
  - Damage Relationships with Government Officials
  - Risks / Costs Lower with Ongoing Compliance
- Consider Issues regarding Transparency

# Overview of Political Laws - Importance of Compliance

The New York Times  
nytimes.com

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December 23, 2006

## U.S. Researcher Penalized for Drug Maker Ties

By THE ASSOCIATED PRESS

BALTIMORE, Dec. 22 (AP) — A federal researcher was ordered Friday to forfeit \$300,000 and perform 400 hours of community service but will not have to pay a fine for failing to disclose consulting work with the pharmaceutical giant Pfizer.

The researcher, Pearson Sunderland III, an Alzheimer's specialist who ran a geriatric research unit at the National Institute of Mental Health, part of the National Institutes of Health, pleaded guilty this month to a misdemeanor conflict-of-interest charge.

Mr. Sunderland admitted that he shared thousands of the institute's human tissue samples with Pfizer at the same time he was paid as a private consultant. Many of the samples are highly sought-after in Alzheimer's research.

Mr. Sunderland told Judge Frederick Motz of Federal District Court at the sentencing that he did not have a good explanation for his actions.

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# *Lobbying*

- What do lobbying laws regulate?
  - “Attempting to influence” government “action”
  - Always covers legislature
    - “Legislative action”
  - Often (and increasingly) covers executive branch
    - “Executive action”
    - “Administrative action”

# Lobbying

- What do lobbying laws require / restrict?
  - Registration Requirements
    - Lobbyists
      - In-house and Contract Lobbyists / Consultants
      - Generally compensation, activity (time), and / or expenditure threshold
      - Authorization
    - and (often) “Principals,” “Clients,” “Employers”
    - Identify substance of lobbying efforts
    - Timing can be key



# *Lobbying*

- What do lobbying laws require / restrict (cont.)?
  - Reporting Requirements
    - Lobbyists and / or Principals
      - May be monthly, bi-monthly, semi-annual, etc.
      - Issues / actions lobbied
      - Expenditures made in connection with lobbying efforts
      - “Gifts” -- meals, receptions, etc. provided to officials
      - Political contributions
  - Recordkeeping requirements
  - Contingency fees often prohibited

# *Lobbying*

- What are the key potential “triggering events”?
  - Meeting with, talking to, or writing a public official
  - Hiring a contract lobbyist
  - Sponsoring / participating in educational events for officials
  - Paying for an official’s meal, golf, drinks
  - Providing samples / product giveaways to officials
  - Establishing grassroots lobbying effort

# Defining “Lobbying” Louisiana Advisory Opinion



2005-560a

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Caption:

January 17, 2006

John Bentivoglio  
King & Spalding LLP  
1700 Pennsylvania Avenue, N.W.  
Washington, DC 20006-4706

RE: Ethics Board Docket No. 2005-560

Dear Mr. Bentivoglio:

The Louisiana Board of Ethics, at its January 12, 2006 meeting, considered your revised request for an advisory opinion concerning 1) whether the educational and detailing practices of pharmaceutical and biotechnology employees directed toward physicians and other health care professionals practicing or

affiliated with public hospitals, which are conducted for the purposes of educating practitioners about available pharmaceutical products and the risks and benefits associated with drugs to better enable practitioners to make appropriate patient treatment choices, is considered “lobbying.”

The Board concluded, and instructed me to inform you, that the educational and detailing practices of pharmaceutical and biotechnology employees directed toward physicians and other health care professionals practicing or affiliated with public hospitals, which are conducted for the purposes of educating practitioners about available pharmaceutical products and the risks and benefits associated with drugs to better enable practitioners to make appropriate patient treatment choices, is considered “lobbying.”

The Board of Ethics, at its January 12, 2006 meeting, considered your revised request for an advisory opinion concerning 1) whether the educational and detailing practices of pharmaceutical and biotechnology employees directed toward physicians and other health care professionals practicing or affiliated with public hospitals, which are conducted for the purposes of educating practitioners about available pharmaceutical products and the risks and benefits associated with drugs to better enable practitioners to make appropriate patient treatment choices, is considered “lobbying.” La. R.S.49:72(6) defines “lobbying” as “any direct act or communication with an executive branch official, the purpose of which is to aid in influencing an executive branch action.” State hospitals are agencies under the Department of Health and Hospitals within the Executive Branch of the State of Louisiana; therefore, state hospital employees are considered executive branch officials. La. R.S.49:72(2) defines “Executive branch action” as “any act by an executive branch agency or official to effectuate the public powers, functions, and duties of an executive branch official or an executive branch agency.”(Emphasis added.) Prescribing medication to patients is a duty of a physician employed by a state hospital. Thus, prescribing a particular medicine would meet the definition of “executive branch action.” Therefore, any direct act or communication with executive branch officials in connection with the education or promotion of pharmaceutical products constitutes “lobbying.” Accordingly, pharmaceutical industry employees are required to register as lobbyists within five days of making “expenditures” of more than \$500. An “expenditure” is defined as “the gift or payment of money or anything of value when the amount of value exceeds ten dollars for the purchase of food, drink, or refreshment for an executive branch official and any gift or payment permitted by R.S. 42:1123(13) when the value exceeds ten dollars for the purpose of

# *Gifts & Entertainment*

- What do ethics laws regulate?
  - Providing (or offering) “gifts” to public officials
    - Meals, entertainment (golf), attendance at receptions
    - Product samples
    - Health screenings / informational materials
    - Event mementos, giveaways
    - Travel / lodging / transportation

# *Gifts & Entertainment*

- What do ethics laws require / restrict?
  - Gift limits
    - Usually annual
    - Dollar cap on amount official may receive from a donor
    - Often prevent gifts within limits that “present appearance of impropriety”
  - Prohibited sources
    - Often party with interests before agency or official
  - Prohibition on hiring/paying government officials
    - Not something most SGA personnel will/should do

# *Gifts & Entertainment*

- What do ethics laws require / restrict (cont.)?
  - Donor reporting requirements
    - Lobbyists / lobbyist employers, others
    - Specific dollar amounts and attendees
    - Valuation of gift often an issue, and often dealt with specifically in law
  - Notification of / reporting by public official

# *Gifts & Entertainment*

- What are the key potential “triggering events”?
  - Paying for an official’s meal, drinks, golf, travel, etc.
  - Hiring an official
  - Holding, or contributing to, an event, reception, etc., that public officials will attend
  - Providing health screenings / educational services / informational materials to officials
  - Providing free product samples to an official
  - Providing an official with use of personal or corporate property, facilities, etc.

# *Consulting Arrangements*

- Many state ethics laws restrict or prohibit hiring/paying government officials for consulting (e.g., clinical research, promotional speaking, and/or consulting services generally)
- Other states permit such relationships, provided certain conditions are met
  - **Texas** -- permits consulting arrangements between companies and state HCPs so long as:
    - HCP is hired because of his/her “expertise or knowledge,” (not because of his/her official position)
    - payment reflects actual value of services performed



# *Consulting Arrangements*

- **Louisiana** -- law generally prohibits state HCPs from performing compensated services for any person who does business with, is regulated by or who has economic interests that may be “substantially affected” by the performance of the state employee’s duties
  - However, an exception expressly permits faculty and staff members of state universities to be compensated by any person for consulting services related to the employee’s academic discipline or expertise
  - Consulting services also must be approved and conducted in accordance with University procedures

## State Political Laws Affecting Pharmaceutical Sales and Marketing Activities

This chart provides a general summary of selected state laws. It is not intended to be and should not be relied upon as legal advice.

State	Scope		Gifts to Healthcare Professionals							Compensation of Healthcare Professionals			
	HCP generally subject to ethics laws?	P&T generally subject to ethics laws?	Restrictions on meals and beverages?	Meals and beverages in presence of donor exempted?	Meals and beverages in connection with speech, panel exempted?	Meals and beverages in connection with outside work exempted?	Where permitted, specific dollar limit on meals and beverages to HCP?	Other restrictions on other gifts/items of value?	Donor liability?	Generally permitted to hire HCP for clinical research?	Generally permitted to hire HCP for promo speaking?	Generally permitted to hire HCP for consulting?	Donor liability?
Alabama	Apparently excluded as employees of hospitals or other "healthcare corporations."	Apparently yes, if "appointed."	Yes (but not for HCP exempt from ethics laws).	Yes, if provided at "social occasion."	No.	No.	"Seasonal gifts" apparently subject to \$100 per occasion/\$250 per year limit if not otherwise exempted.	Yes.	Yes, for providing a public official or employee a "thing of value" to "influence official action."	Yes.	Yes.	Yes.	N/A
California	Yes, if deemed to be "designated employees" by employing agency.	Unclear, but might be exempt as members of entities that function solely in advisory capacity.	Yes.	No.	Yes.	No.	Subject to \$360 per year limit under certain circumstances.	Yes.	Yes.	Yes.	Yes.	Yes.	Yes.
District of Columbia	Yes.	Unclear, but apparently no.	Yes.	No.	No.	No.	No.	Yes.	Yes.	Appears to be permissible under certain circumstances.	Appears to be permissible under certain circumstances.	Appears to be permissible under certain circumstances.	No.
Florida	Yes, if "employees" of the state.	Unclear.	Yes.	No.	No.	No.	No.	Yes.	No.	No, where the employer "does business with" the state facilities employing the HCP.	No, where the employer "does business with" the state facilities employing the HCP.	No, where the employer "does business with" the state facilities employing the HCP.	No.



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Louisiana	Yes.	Yes.	Yes.	Yes.	No.	No.	No.	Yes.	Yes.	No, <i>inter alia</i> , where HCP's duties entail writing prescription or treating patients.	No, <i>inter alia</i> , where HCP's duties entail writing prescription or treating patients.	No, <i>inter alia</i> , where HCP's duties entail writing prescription or treating patients.	Yes.
Maine	No.	No.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes. (Apparently not governed by ethics laws.)	Yes. (Apparently not governed by ethics laws.)	Yes. (Apparently not governed by ethics laws.)	N/A
New York	Yes.	Might be covered if they receive compensation other than on a "per diem" basis.	Yes.	No.	Yes.	No.	Yes. Public Employee Ethics Reform Act of 2007 limits provision of meals to those of "nominal value."	Yes.	Yes.	Apparently permissible under certain circumstances.	Apparently permissible under certain circumstances.	No.	
Oregon	Yes.	Yes, if appointed by the state.	Yes.	Yes.	Unclear.	Possibly permissible as gifts provided to others who are not public officials "on the same terms and conditions."	Subject to \$100 per occasion/\$250 per year limits under certain circumstances.	Yes.	Yes, where a person with a "legislative or administrative" interest provides an impermissible gift to a public official.	Unclear, but appears to be permissible under certain circumstances.	Unclear, but appears to be permissible under certain circumstances.	Unclear, but appears to be permissible under certain circumstances.	No.
Tennessee	Yes, if "employees" of the state.	Unclear, but might be covered as members of a "state body" in the executive	Yes.	Yes, under certain circumstances.	Yes, under certain circumstances.	Yes.	Yes, under certain circumstances.	Yes.	Yes.	Yes.	Yes.	Yes.	Yes.



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		branch.											
Texas	Yes.	Yes, depending on terms of appointment.	Yes.	No.	No.	No.	No.	Yes.	Yes, for a gift that is given that the donor knows the public servant is prohibited by law from accepting.	Appears to be permissible so long as HCP is hired because of "expertise or knowledge" (and not his or her official position), the payment reflects the actual value of the services performed, and HCP does not use state resources unless specifically permitted by agency.	Appears to be permissible so long as HCP is hired because of "expertise or knowledge" (and not his or her official position), the payment reflects the actual value of the services performed, and HCP does not use state resources unless specifically permitted by agency.	Appears to be permissible so long as HCP is hired because of "expertise or knowledge" (and not his or her official position), the payment reflects the actual value of the services performed, and HCP does not use state resources unless specifically permitted by agency.	Yes, for providing compensation to HCP that the employer knows the public servant is prohibited by law from accepting

# ***New Ethics Law Developments***

- **New Mexico** - recently enacted “Gift Act” (SB 931) prohibits state employees from accepting any gift with a market value greater than \$250 from a “restricted donor,” including:
  - a person seeking to do or conducting business with the state employee’s agency
  - a person who has a matter pending before the state employee’s agency over which the employee has discretionary authority
  - a lobbyist

*2007 N.M. Adv. Legis. Serv. §§ 10-16B-2(D), 3(A)*

- **New York** - the Public Employee Ethics Reform Act of 2007 amended NY’s ethics law to change the prohibition on gifts of \$75 or more per calendar year to prohibit gifts of “more than nominal value” (not defined by statute) to state employees from a donor who is regulated by, does business with, or lobbies the employee’s agency

*Public Employee Ethics Reform Act of 2007 (effective Apr. 25, 2007) (amending N.Y. Pub. Off. Law § 73(5))*

# *Vendor Access Policies*

- **Academic Centers** - Association of American Medical Colleges encouraging academic medical centers to adopt policies regulating industry interaction with HCPs
  - JAMA published article in January 2006 proposing academic medical centers adopt industry interaction policies (JAMA Vol. 495 No. 4 at 429-433).
  - Academic medical centers have adopted policies, including:
    - Stanford Medical Center -- effective October 1, 2006
    - Hospital of the University of Pennsylvania -- effective July 1, 2006
    - Yale Medical Group -- effective May 18, 2005
- **State System Policies** - Florida's Jackson Health System (JHS) "Vendor and Visitor Activity Policy" went into effect May 8, 2007

# ***FL's JHS Vendor Access Policy***

- Policy applies to all vendors, specifically including “Pharmaceutical and Supply Sales Representatives”
- Vendors must report certain information, including name, company address, nature of business, necessity of lobbyist registration with Miami-Dade County and other contact information for approval by the JHS Department of Procurement Management
- Vendors must have a scheduled appointment to visit JHS
- Vendors are not permitted to attend conferences where protected patient health information is shared
- Vendors may not see patients, or any patient health information (e.g., attend rounds, review charts or medical records)

# ***FL's JHS Vendor Access Policy***

- Vendors are prohibited from providing “payment in the form of food, gifts, or promotional materials, or in support of any JHS conference or meeting” and from providing food in any JHS building
- Direct-to-Consumer Marketing is prohibited, and promotional materials may not be placed in patient care areas
- Vendors are prohibited from discussing non-formulary items with medical staff
- “Sample drugs” may not be used or issued to patients by sales reps or JHS personnel, or stored within any JHS facility
- Vendors must register as lobbyists with Miami-Dade County before “seeking to influence any aspect of JHS decision-making with respect to their product or service”