PHARMACONGRESS 2008

COMPLIANCE OVERVIEW: LAWS, REGULATIONS, SETTLEMENTS & GUIDANCES

Preconference I:
Pharmaceutical Regulatory
and Compliance Basics

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October 27, 2008
Washington, DC

"Corporate compliance officers are very much today's corporate 'fire personnel.' They are often the company's 'first responders' and must focus on both ***proactive and reactive*** *efforts to be effective. Proactive efforts need to emphasize the complementary goals of* ***crime prevention and corporate ethical behavior****. Reactive efforts measure* ***how well a corporation reacts*** *when it learns that questionable and potentially illegal corporate conduct has occurred."*

US v. Caputo (7th Cir. 2008)

ROADMAP

- Specific Risk Areas
- History of How We Got Here
- Underlying Legal Bases
- Summary of Cases
- Codes, guidances, states, Congress, institutions
- Observations
- Horizon
- Prophylactic Steps

SPECIFIC RISK AREAS

- Federal Anti-kickback Law
- State Anti-kickback laws
- Federal False Claims Act
- State False Claims Acts
- Off-label Promotion
- Promotional Rules
- DTC Advertising
- Samples
- Adverse Event Reporting
- Integrity of Data, Including Medicaid Drug Rebate, Best Price, Etc.
- False, Misleading Statements Re Efficacy or Safety of Products
- Patient Privacy (HIPAA)
- Foreign Corrupt Practices Act
- Securities Laws
- Data Mining Restrictions
- Clinical Trials
- Payments to HCP Customers, including Consulting and Advisory Payments
- Discounts (Unprotected)
- Product Support Services
- Preceptorships
- Speaker Programs
- Ad Boards
- Disclosure of Financial Relationships
- Payments to PBMs
- Pricing: AWP/ASP
- Relationships w/Formulary Comm. Members
- Formulary Placement Payments
- Switching
- Payments for Detailing
- Business Courtesies, e.g., Gifts and Entertainment
- Value-added Services
- Relationships With Sales Agents
- Inappropriately Providing Nominally Priced Drugs
- Use of Medical Science Liaisons
- Tainting of Providers' Judgment
- Ghost-writing
- Good Manufacturing Practices
- State Disclosure Laws
- State Gift Limitations Laws
- State Consumer Fraud laws
- State Pedigree Laws
- State Rep Licensing Laws

Why Are We Here Today?

PHARMACEUTICAL MANUFACTURER SETTLEMENTS

COMPANY	Year	$M	Kickbacks	False Claims	Samples	Off-Label Promotion	Medicaid Drug Rebate
TAP	2001	875	X	X	X		
Bayer I	2001	14		X			X
AstraZeneca	2003	600	X		X		
Bayer II	2003	257					X
Glaxo	2003	87.6					X
Pfizer I	2004	430		X		X	
Schering I	2004	345					X
Serono	2005	704	X			X	
King	2005	124					X
Lilly	2005	36				X	
Schering II	2006	435	X	X		X	X
Intermune	2006	36				X	
Pfizer II	2007	34.7	X			X	
Cell Therapeutics	2007	10.5	X	X		X	
Purdue	2007	635				X	
Medicis	2007	9.8		X		X	
Jazz	2007	20		X		X	
Sanofi-Aventis	2007	190	X	X			
BMS	2007	515	X	X		X	X
Merck	2008	650	X	X			X
Otsuka	2008	4		X		X	
Biovail	2008	22	X				
Cephalon	2008	425		X		X	

MEDICAL DEVICE MANUFACTURER SETTLEMENTS

COMPANY	Year	$M	Kickbacks	False Claims	Off-Label Promotion	Adverse Events
Guidant	2003	94				X
Orthofix	2003	1.6		X	X	
Medtronic	2006	40	X			
Zimmer Inc.	2007	169.5	X			
Depuy Orthopaedics	2007	84.7	X			
Smith & Nephew Inc.	2007	28.9	X			
Biomet Orthopedics	2007	26.9	X			
Stryker Orthopedics	2007	0	X			
AbTox*	2008	17				
Medtronic Spine	2008	75		X		

*AbTox went to trial.

	PHARMACEUTICAL/PBM/DISTRIBUTOR SETTLEMENTS						
COMPANY	Year	$M	Kick-backs	False Claims	Controlled Substances	Shorting	Switching
CVS	2001	4		X		X	
Eckerd	2002	5.8		X		X	
Rite-Aid	2004	7		X			
AdvancePCS	2005	138.5	X	X			
Kroger	2005	7			X		
Medco	2006	155	X	X		X	X
Walgreens	2008	9.9		X			
McKesson	2008	13.3			X		
CVS Caremark	2008	37.5					X

How Did We Get Here?

HISTORIC VIEW

- Kennedy Hearings (1991)
- AMA Code revisions and educational campaign (1991; clarifications 1992, 2002, 2003)
- PMA Code (now PhRMA) (1991)
- HIMA Code (now AdvaMed) (1993)
- OIG Special Fraud Alert for Pharmaceutical Industry (1994)
- PhRMA Code (May 2002)
- OIG Guidance to Pharmaceutical Industry (April 2003)
- US Sentencing Commission Guidelines (2004 revisions)
- PhRMA Code Revisions (July 2008)

What Are the Underlying Legal Bases?

STATUTORY AND REGULATORY BASES

- Antikickback Statute
- False Claims Act
- Food, Drug & Cosmetic Act

ANTI-KICKBACK LAW

ELEMENTS OF A VIOLATION

- Knowingly
- Offering/receiving or paying/soliciting
- Remuneration (including kickback, rebate, bribe)
- In cash or in kind
- Directly or indirectly
- To induce someone to refer a patient or to purchase, lease, or order or recommend these activities
- Any goods or services
- Reimbursable under federal healthcare programs, e.g., Medicare/Medicaid

EXCEPTIONS

- Statutory and Regulatory (Safe Harbors)
  - Discounts
  - Personal Services
  - GPOs

PENALTIES

- Fines (up to $250,000 for individuals and $500,000 for companies)
- *Criminal* prosecution of corporations *and* individuals (up to 5 years' imprisonment)
- BOTH
- Civil penalties
  - Exclusion from federal health care programs
  - Civil monetary penalties: $50,000 for each act plus 3x amount of illegal remuneration

FALSE CLAIMS ACT

- Prohibits a person from knowingly submitting or *causing to be submitted* claims, making false statements to secure payment by the federal government
- Penalties
  - Civil penalties of up to $10,000, *PLUS* 3X amount of damages sustained
    - No specific intent required
    - Can cover mfrs/consultants providing incorrect coding advice

DRUG LAW

- Food, Drug & Cosmetic Act
- Prescription drug marketing and advertising regulations (21 CFR)
- Regulated by
  - Division of Drug Marketing, Advertising and Communications (DDMAC) in the
  - Center for Drug Evaluation and Research (CDER) at the
  - Food and Drug Administration (FDA)
- Off-label cases have involved allegations of off-label promotion under the FDCA (and False Claims Act)

REMEDIES/ENFORCEMENT POWERS

- Remedies
  - Regulatory letter (a/k/a notice of violation or untitled letter)
  - Warning letter
  - Other remedies:
    - Immediate cessation of all materials containing violative statements or graphics
    - Dear Doctor letters
    - Corrective advertising
    - Pre-clearance
- Enforcement Powers
  - Injunction
  - Seizure
  - Consent decree
  - Fines
  - Criminal prosecution

OTHER IMPORTANT LAWS

- HIPAA
- Medicaid Drug Rebate Statute
- Foreign Corrupt Practices Act
- Prescription Drug Marketing Act
- Securities Laws
- Prescription Drug Marketing Act

How is all of this relevant to my compliance program?

MANUFACTURER SETTLEMENTS

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Medtronic Spine	2008	75		X				
Merck	2008	650	X	X			X	
Otsuka	2008	4		X		X		
Biovail	2008	22	X					
Cephalon	2008	425		X		X		
Pfizer III	2008	60M				X		

TAP (2001)

- Lupron®
- $875M settlement
- Individuals – employees and physicians – indicted (dismissed and acquitted in 2004)
- 3 individuals pled guilty
- Allegations included violations of:
  - Anti-Kickback Statute, False Claims Act, and PDMA
  - Alleged illegal remuneration
  - Marketing the spread
  - Inappropriate unrestricted educational grants
  - Free or nominally priced drugs to induce prescribing of Lupron
  - Distribution of samples “knowing and expecting” that physicians would seek reimbursement
  - Free items (such as computers and fax machines)
  - Free travel and entertainment (including golf outings)
  - Payments for attendance at seminars
  - Free consulting on practice management
  - Contract management fees
- 7 year CIA
  - TAP requested, and was granted, early dismissal of the CIA
  - TAP is now part of Takeda

PFIZER (2004)

- Neurontin®
- $430M (2004)
- Note: Relator, Dr. David Franklin, was a Medical Science Liaison
- Government's Concern: Concerted effort to promote Neurontin off-label
  - Pushed the drug in higher doses forms –insufficient data to support seeking FDA approval
  - Sales reps probed doctors on off-label uses: "Doctor, are you aware that over half the patients on Neurontin do not have epilepsy?"
  - Used physician conferences to push off-label indications – such as targeting pain and psych market.
  - Had specifically determined not to seek FDA approval for the additional indication

PFIZER 2004 (cont'd)

- Evidence
  - Voice mail transcription (to MSLs): "Medical Liaisons, this is [the northeast Associate Director]. I am calling in regard to the – you know, there's a Neurontin push that's supposed to be on. ….So, what we need to do is focus on Neurontin. When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do. Cause I'm embarrassed. But I'm embarrassed about where we are with Neurontin. We've got to take it into our own hands and really kick some ass on it, all right? Let's do it up."

  - It recommended that FDA approval of Neurontin for psychiatric indications NOT be pursued given the limited patent protection and market prospects.

SERONO (2005)

- Serostim®
- $704M settlement
- Count 1: Marketing of Serostim® for AIDS wasting
  - Market declining due to protease inhibitors
  - Allegations company conspired with a medical device mfr to market computer software packages for calculating body cell mass and diagnosing AIDS wasting
    - Device not approved: earlier device changed
    - Increased the market for Serostim
    - Employees directly administered tests to patients
    - Induced Medicaid claims
- Govt's concern: Patient Safety. Vulnerable patient population receiving unnecessary drugs

SERONO (2005) (cont'd)

- Count 2: Offering of incentives to HCPs to purchase Serostim
  - In 1999, BU was falling significantly short of its sales goals
  - Per management: needed to "dig their way out" of this fiscal crisis
    - Devised the "$6m-6 Day Plan": involved offering financial incentives to high prescribing physicians and thought leaders to obtain the requisite number of prescriptions
    - Offered an all-expenses paid trip for HCPs and guests to a conference in Cannes

ELI LILLY (2005)

- Evista®
- $36M Consent Decree
- Alleged illegal promotion of Evista, an osteoporosis drug for off-label uses (prevention of breast cancer and cardiovascular disease)
  - Training of sales force in off-label uses
    - "Best practices" videotape
    - Prompted questions by sales force
- NOTES
  - Important to review training materials
  - Product now approved for reducing risk of breast cancer

SCHERING II (2006)

- $435M settlement
- Resolution of range of federal and state issues
- Alleged off-label promotion
- Alleged unlawful promotion
  - Preceptorships, sales goals/compensation, entertainment, advisory boards, placement of clinical trials, payments to physicians
- Alleged False Statements to FDA and CMS
  - False statement contained in letter to DDMAC indicating problems were isolated and being addressed
- NOTES
  - Strong compliance response, changes in corporate culture
  - Addendum to 2004 settlement

PURDUE (2007)

- Oxycontin®
- $634.5M (Proposed Plea)
- Alleged introduction of a misbranded drug into interstate commerce
  - Received Warning Letter
  - Allegation that sales reps downplayed risks of OxyContin
    - Less addictive, less subject to abuse and diversion
  - One count of misdemeanor misbranding against CEO, General Counsel, and Exec. VP of Worldwide R&D
    - Aggregate $35M against individuals
- *Park* doctrine applied

CELL THERAPEUTICS (2007)

- Trisenox®
- $10.5M
- Alleged off-label uses of Trisenox for certain cancers
- NOTES:
  - Small pharma
  - Focus on investigator-initiated studies
  - Requires company to notify OIG if it develops a marketable drug

MEDICIS (2007)

- Loprox®
- $9.8M
- Off-label promotion of Loprox, topical fungicide, approved for use in patients over 10, to treat diaper rash
- NOTE
  - Resolution of prior activity: Medicis sold pediatric unit in 2004

MERCK (2008)

- $650M
- Alleged Unlawful Promotion
  - Provided kickbacks to HCPs through sales programs and activities
  - Money provided to physicians was not for bona fide services and was excessive, not fair market value
- Alleged kickbacks in form of steep discounts to hospitals (Zocor, Vioxx)
  - Inducement for hospital to achieve certain level of purchasing
  - Prices not reported to Medicaid
- Alleged unlawful incentives to hospitals to encourage primary use of Pepcid
  - Intended to obtain spillover business after patient left hospital
- Note: Involved 2 separate lawsuits

BIOVAIL (2008)

- Cardizem®
- $22M
- Paid HCPs $1000 to enroll patients in experience program
  - HCPs required to complete 2-page, 10 multiple choice questionnaire that took approximately 10 minutes to finish for $250
  - HCPs paid additional $750 if they enrolled between 11 and 15 patients
  - Visits were routine and required no additional work for HCPs
  - No additional scientific data were anticipated
- NOTE:
  - Management changed; new managers not implicated

PFIZER (2007)

- $34.7M settlement
- Genotropin®
- Allegations
  - Illegal off-label promotion of Genotropin, human growth hormone, for anti-aging, cosmetic, and athletic performance uses
  - Illegal offering of excessive payments on a PBM contract to obtain improved formulary position
- Notes:
  - Acquisition-associated self-disclosure by Pfizer a factor here
    - Pfizer not involved and CIA already in place
  - Whistleblower suit remains
  - Permanent exclusion of Pharmacia & Upjohn, Inc.

JAZZ PHARMACEUTICALS (2007)

- Xyrem®
- $20M
- Settlement focused on illegal promotion of Xyrem® (GHB) for unapproved uses
  - Approved for use in cataplexy and excessive daytime sleepiness in narcolepsy patients, but subject to abuse as a recreational and "date rape" drug
    - Black box warning and extensive risk management program
    - Allegation that company sought to expand market to fatigue, chronic pain, bipolar, depression, suggested pediatric use
  - Prosecutors focused on sales calls on physicians who do not specialize in narcolepsy, and off-label written materials
- NOTES
  - Physician speaker arrested; sales manager pled guilty
  - Speaker provided reimbursement advice on off-label uses
  - Made statements that Xyrem was "as safe as table salt"
  - Physician/speaker made over $100K from Jazz for presentations
  - Required separation of Law Department and Compliance Department
  - Entered into non-prosecution agreement
  - Jazz recently purchased Orphan Medical

BRISTOL-MYERS SQUIBB (2007)

- $515M
- Resolution of variety of allegations involving various drugs
- Alleged Off-label Promotion (Abilify)
  - Promoted Abilify to treat children and dementia-related psychosis (Black Box warning for dementia-related psychoses)
  - Directed sales force to call on other specialists
  - Created sales force to sell to nursing homes for dementia-related psychosis patients
- Alleged Unlawful Promotion
  - BMS paid illegal remuneration to HCPs to induce purchase of drugs
    - Consulting fees and expenses to participate in programs, advisory boards, and preceptorships
    - Provided incentives, including stocking allowances and free goods, to retail pharmacies and wholesale customers
- Alleged unlawful setting of fraudulent prices for numerous drugs
- Alleged unlawful misreporting of best price (Serzone)
- NOTES
  - 7 whistleblowers
  - Marketing the spread (like TAP)
  - CIA
  - Co-promote partner involved

OTSUKA (2008)

- Abilify®
- $4M
- Alleged Off-label Promotion
  - Knowingly promoted Abilify off-label to treat children and dementia-related psychosis
  - See BMS

ORTHOPEDIC DEVICE MFRS SETTLEMENTS (2007)

- $311M total for 5 cases
- Manufacturers: Zimmer, Inc., Depuy Orthopaedics, Biomet, Smith & Nephew, and Stryker
- 5 companies make 95% of hip and knee implants
- Alleged Illegal Marketing
  - Used sham consulting agreements and other tactics to induce use of their products
- 4 companies entered into Deferred Prosecution Agreements (DPAs)
- Stryker entered into a Non-prosecution Agreement with similar terms
- Significant new provisions:
  - appointment of a federal monitor required
  - requirement that companies include in their agreements with physician customers a provision that the physicians disclose the relationship with their patients
  - requirement that companies post on their websites the names of all consultants and their compensation
  - requirement that each company determine in advance, through the conduct of a needs assessment, what training and product development work they actually need

CEPHALON (2008)

- $425M
- Illegal off-label promotion allegations
  - Trained reps to promote off-label, ignoring restrictions on label
  - Targets included other specialists
  - Structured quotas and bonuses to require off-label sales
  - Trained reps, medical professionals to speak off-label
  - Funded CME programs to promote off-label uses
- Involved Gabitril®, Actiq®, and Provigil®
- Patient Safety
- New Provisions
  - Cephalon must send doctors letter
    - Advising them of the resolution of the case
    - Must post payments to doctors on its website
    - Board, top management must regular certify compliance with CIA provisions
- NOTE:
  - First settlement since device cases

ABTOX (ABTOX PLAZLYTE STERILIZATION SYSTEM) (2008)

- *US v. Caputo (*7th Cir. 2008)
- CEO and VP & Chief Compliance Officer sentenced to 10 and 6 years, respectively
- Illegal Off-label Promotion
  - Told hospitals they had received FDA approval of a large sterilizer, when in fact, FDA had approved only the smaller device
- Did not report adverse events
- Patient Safety:
  - At least 25 patients suffered corneal damage
  - Company had knowledge that sterilizer left residue on instruments
- Required to reimburse hospitals $17 Million
- NOTE: Company declared bankruptcy

CODES, GUIDANCES, STATES, CONGRESS, INSTITUTIONS

AMA CODE

- Gift primarily for benefit of patient
- Gifts *not* of substantial value ($100 or less)
- No cash payments
- Modest hospitality acceptable

CURRENT PhRMA CODE

- Topics
  - Informational Presentations
  - Third-Party Educational Conferences/Professional Meetings
  - Consultants
  - Speaker Training Meetings
  - Scholarships and Educational Funds
  - Gifts
- Underlying Principle: Financial arrangements may never be given or offered in exchange for prescribing products nor in a manner that would interfere with HCP's independence in prescribing.
- Impact of Code (per OIG Guidance): **"**Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse **and** help demonstrate a good faith effort to comply with" the law. **(And now the states have weighed in.)**

REVISED PHRMA CODE

- Effective January 1, 2009
- No More
  - Tshatshkes (all gifts must be educational)
  - Restaurant meals (but occasional in-office meals still ok)
- New
  - Reps must be trained on applicable laws, regs, PhRMA Code re interactions with HCPs, and tested periodically
  - Mfrs to take appropriate personnel actions, when necessary
  - CEO and CCO to certify annually that they have processes in place to implement the Code
  - Mfrs to obtain external verification that compliance program is working
  - PhRMA to put on website mfrs' intentions to adopt Code, PhRMA, contact info for CCO, and information re mfrs' annual certifications
  - New standards for use of prescriber data
  - Importance of transparency
- Enhancements/modifications
  - Additional standards for CME programs
  - Additional standards for agreements with HCPs, including disclosures re HCPs on formulary committees, develop clinical practice guidelines

SENTENCING GUIDELINES

- Effective 1991
- Purpose: To provide for evenhanded sentencing of crimes
- Guidelines provide judges with formulas for penalties for mitigating, aggregating circumstances (including jail time) if certain conditions exist or are missing (e.g., effective compliance program)
- Created the 7 Elements
- 2004 amendments added new element
  - Perform **risk assessments** on an on-going basis to determine likelihood of compliance violations occurring and take steps to address such risks
- Important: Compliance Program must be ***effective***
- Use results of assessments to:
  - Modify the Compliance Program
  - Prioritize compliance efforts and available resources
- Corporations should have *knowledge* of:
  - Major risks of illegal conduct
  - Elements of compliance program that address those risks
  - Problems encountered
- Corporations should have *oversight* of activities:
  - Proactively search for problems
  - Analyze information gathered
  - Take corrective actions and monitor implementation
- Corporations should inculcate a culture of compliance

OIG GUIDANCE

- Stated Purpose: To help companies prevent health care fraud and abuse by promoting a high level of ethical and lawful corporate conduct.
- 7 Elements:
  - Designation of a Compliance Officer
  - Development of policies and procedures
  - Conducting of education and training
  - Creation and maintenance of an effective line of communication between the CO and all employees; establishment of a hotline
  - Auditing and monitoring
  - Conducting of internal investigations, identifying wrongdoings, taking of appropriate personnel actions
  - Self-reporting

OIG GUIDANCE: RISK AREAS IDENTIFIED

- KICKBACKS
  1. Relationships with purchasers and their agents
     a. Discounts and other remuneration to purchasers
        1. Discounts
        2. Product Support Services
        3. Educational Grants
        4. Research Funding
        5. Other remuneration
     b. Formularies
        1. Relationships with formulary committee members
        2. Payments to PBMs
        3. Formulary placement payments
     c. AWP
  2. Relationships with referral sources
     a. Switching
     b. Consulting and Advisory payments
     c. Payments for detailing
     d. Business courtesies
     e. Educational & research funding
  3. Relationships with Sales Agents
- INTEGRITY OF DATA SUBMITTED TO GOVERNMENT
- SAMPLES

OIG GUIDANCE: GRANTS

- MED ED GRANTS
  - Companies should separate their grant making functions from their sales and marketing functions (in order to reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately)
  - Mfrs should establish objective criteria for making grants that do not take into account volume or value of purchases made by or anticipated from, the recipient.
  - Companies should have no control over the speaker or content of the educational presentation.
- RESEARCH GRANTS
  - Mfrs should develop contracting procedures clearly separating research contracts from marketing (because research contracts originate in sales or marketing “are particularly suspect.”)
  - Also, research grants can be misused to induce purchase of business without triggering best price obligations.

ACCME GUIDELINES

- ACCME Guidelines Criteria for accredited CME Programs (2007)
  - independent
  - objective
  - balanced and
  - include scientific rigor in content development
  - Mfrs not to have input into content or selection of speakers, unless requested
- Critical Revisions to ACCME Guidelines
  - Sponsors may not request suggestions for speakers or topics from mfrs since it is unacceptable to act upon their suggestions
    - Mfrs may not provide comment on accuracy of content
    - May not review content prior to CME program

CONGRESSIONAL ACTIONS: GRANTS

- June 10, 2005: Congress requested 23 drug makers to explain marketing practices of giving grants
  - Questioning whether these "educational grants" are more focused on product promotion than education.
  - Want to ensure that grants aren't just a "backdoor way to funnel money to doctors and other individuals who can influence prescribing and purchasing of particular prescription medicines, including off-label prescriptions."
  - "Grants need to be driven by good intentions instead of motivation for larger profits."
- January 11, 2006: Letters to 22 companies and separate letter to J&J and expanding the investigation into grants to advocacy organizations, AMCs, and state agencies
  - Both letters: Senators "are concerned that sales and marketing personnel may influence the awarding of grants in a way that favors those individuals or organizations that are known to advocate use of specific product(s)."
  - Also, expressed concern with grants to professional and patient advocacy organizations as well as certain grants to AMCs and state agencies.
  - Recognized that many companies have modified their grants P&Ps following the PhRMA Code and OIG Guidance.
  - J&J letter: focuses specifically on pediatric use of Propulsid (not labeled for use in children)

CONGRESSIONAL ACTIONS: GRANTS (cont'd)

- Senate Finance Committee Staff Report, "Use of Educational Grants by Pharmaceutical manufacturers" Final Report issued on April 2007
  - Concluded:
    - *Manufacturers' use of educational grants "as a way to increase the market for their products . . . is of particular concern when the companies use educational grants to encourage physicians to prescribe products for uses beyond their" approval.*
    - *The report notes that companies have "implemented policies meant to rein in these activities," e.g., separating sales and marketing activities.*
    - *The committee continues to have concerns about what appears to be ACCME's ineffective control over programs, noting that "it can take as long as 9 years from the date of a non-compliant educational activity for an educational provider to lose accreditation."*
- *May 1, 2007 Press Release, Senate Finance Committee: "Baucus, Grassley continue work for independence of continuing medical education." Following up on the Staff Report, the Senators sent a letter to the ACCME urging tighter controls*
- *May 1, 2007, Eli Lilly press release, "Lilly to Publish Information on Grants and Contributions." Lilly announced "that it will begin posting online all educational grant funding and other monetary contributions provided to U.S.-based organizations. Lilly is the first pharmaceutical company to disclose its grants to U.S. organizations, which include medical societies, academic centers, patient groups and non-profit institutions."*

CONGRESSIONAL ACTIONS: TIES TO NFPs, HCPs

- Sen. Finance Committee extended reach of grants investigation to industry ties with non-profits, physician reporting of payments, and non-profit ties to HCPs
- October 16, 2008: Sent letters to Cardiovascular Research Foundation and Columbia University (affiliation with CRF)
- Looking into potential conflicts of interests
- CRF Letter:
  - Examining “strong ties between medical device industry and non-profit organizations.”
  - “[C]oncerned that funding form the medical device industry may influence the practices of non-profit organizations that purport to be independent in their viewpoints and actions.”
  - Ties raise “serious questions” as to whether “improper influence” is being exerted upon medical practice.
  - Requesting
    - All financing since 2003 from pharma and device companies
    - Payments or benefits to 22 named physicians
    - CRF’s policies for accepting industry funding
    - Whether restrictions are allowed to be placed on funding, and, if so, itemization of restrictions
    - Communications between CRF and Abbott, Medtronic, Boston Scientific, J&J, Medinol since Jan. 2007

CONGRESSIONAL ACTIONS: TIES TO NFPs, HCPs (cont'd)

- Columbia U. Letter:
  - Examining "strong ties between" pharma and medical device cos and physicians
  - Concluded "lack of transparency" in university physicians' reporting of outside income
  - Requesting
  - information about researchers' disclosures to the university of income from industry
  - Requesting information since 2003
    - Outside income information on same 22 HCPs
    - Funding from Abbott, Medtronic, Boston Scientific, J&J, Medinol, and CRF
    - Relationship between Columbia and CRF and supporting documentation and communications
- Responses due by Oct. 30

STATE LAWS

	MN	CA	VT	DC	WV	ME	LA	FL*	TX	NM	NV	MA
SPENDING LIMITATION	X	X										
SPENDING DISCLOSURE	X		X	X		X						X
PRICE DISCLOSURE		X	X			X			X	X		
AD/MKTG COST DISCLOSURE				X	X	X						
COMPLIANCE PROGRAM		X									X	X
CLINICAL TRIALS						X						
LOBBYING/ LICENSING							X	X				
SAMPLES		NUMEROUS STATES										

*** Miami-Dade County**

FEDERAL SUNSHINE ACT

- Would require mfrs and distributors (drugs and devices) to report annually by June 30 gifts provided "directly or indirectly" to any "covered health entity" in connection with promotional activities
- Report must include
  - Value of payment
  - Date
  - Description
  - Reason (type of payment)
  - Recipient
- Current exclusions
  - Items under $500 annually aggregated
  - Educational materials
  - Training
  - Warranties
  - Discounts
  - Items under $25
  - Charitable contributions (in-kind)
- Preemption for laws "relating to the disclosure or reporting of information regarding payments or other transfers of value . . . ."
- Endorsed by numerous organizations and companies, including PhRMA and AdvaMed
- Transparency
  - Some companies, e.g., Lilly and GlaxoSmithKline, have announced they will post payments to HCPs

INSTITUTIONS

- Journal of the American Medical Association (January 2006) Article
  - 11 HCPs at 6 AMCs, including Harvard, Columbia and Tufts, and several academic associations urged AMCs to more strongly regulate, and in some cases prohibit, many common practices that constitute conflicts of interest with drug and medical device companies.
  - Because “gifts of even minimal value carry influence,” AMCs should place restrictions on:
    - Gifts
    - Samples
    - Drug Formulary Committees
    - CME Support
    - Grants
    - Speakers Bureaus
    - Ghostwriting
    - Consulting
    - Grants
    - Public Posting General Research of Grants and Consulting Arrangements

INSTITUTIONS (cont'd)

- Stanford, among other universities, implemented restrictions on interactions with industry
  - Stanford Industry Interactions Policy (August 2006) regulates, and in some instances, prohibits, certain interactions with industry, including gifts, site access and scholarships and other support for educational activities
- Other university activities:
  - Prohibitions, restrictions, on access
  - Registration Fees
  - Medical Testing, e.g., TB
  - Substantive Testing, e.g., HIPAA and ER protocols
- Other institutions: U. Penn., Yale, Henry Ford, Jackson Health Systems, Vanderbilt, UVA
- Emory: Psychiatrist resigned from gov't funded research studies after failing to reveal $MM in payments from drug cos. (2008)
- Proposed: U. Minn. Med. School (10/08)
- UVA Med Ctr and School of Med adopted broad policy (eff. 10/1/08):
  - Total ban on gifts *except* nominal gifts for educational purpose ok
  - Unrestricted educational grants to UVA Med. Ctr ok
  - Samples ok
- Wisconsin Medical Society (10/08) adopted broad policy:
  - Limiting sampling
  - Requiring disclosure of relationships
  - Banning money from mfrs to CME providers directly
  - Banning speaking for mfrs
  - Banning association in ghostwritten article, banning gifts

HORIZON

- Will we see more of the same? Kickback, off-label, patient safety case?
- Will we see language from device settlements in future CIAs?
- Will we see Cephalon provisions in future CIAs?
- Will there be more device cases?
- Will prosecutors continue to focus on individuals?
- Will there be more state requirements?
- Will there be preemptive federal legislation?
- Will there be a total ban on gifts in institutions?
- Will there be greater transparency, voluntary or required?

WAYS TO AVOID LAND MINES

- Tone at the top is critical: Ensure senior management buy-in to importance of an effective compliance program
- Articulate and publicize zero tolerance for off-label promotion
- Instill ethical behaviors in all activities
- Be prepared with a robust compliance program!
  - Consider using OIG Guidance as foundation and CIAs for risk assessments
  - Develop effective policies and procedures
  - Conduct investigations, monitoring, and auditing
  - Encourage employees to voice concerns
  - Train employees

WAYS TO AVOID LAND MINES (cont'd)

- Install effective policies and procedures for controlling and detecting inappropriate off-label discussions
- Establish stringent review process for all promotional pieces (including training materials)
- Closely monitor all speaker programs
  - Train reps and speakers on handling off-label questions
  - Have in place effective speaker bureau selection process
- Scrutinize compensation design, including incentives
- Scrutinize selection of targets
- Take appropriate disciplinary actions when necessary
- Review clinical studies
- Watch for new state laws and comply timely
- Anticipate compliance trends
- If problem arises, take immediate corrective action, conduct root cause analysis, HR action, and, if warranted, self-disclosure to the government

REMEMBER . . .

- Dispelling Myths: Small companies, medical devices, PBMs, pharmacies
- Government proceeding criminally
- Charges against individuals
  - President
  - General Counsel
  - Compliance Officer
  - Chief Medical Officer
  - Sales Management
  - Physicians
- Areas of Focus: Off-label Promotion, Kickbacks, False Claims, Medicaid Drug Rebates, Grants
- Origins: Many, not all, *qui tam* actions
- Timing: old actions
- Transparency
- Revised PhRMA Code takes effect 1/1/09

ULTIMATELY, IT'S ALL ABOUT ETHICS

QUESTIONS?

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