

2005 Physician Practice Compliance Conference

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&

October 6, 2005

Vendors and Inducements – How Physicians Can Protect Themselves

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THE GOVERNMENT IS VERY SERIOUS ABOUT THIS INITIATIVE

Who is Better to Enforce Internal Compliance or OIG?

Corporate Integrity Agreements

- <http://oig.hhs.gov/fraud/cia/index.html>

FEDERAL FALSE CLAIMS ACT

- Civil Liability (Per False Claim)
 - \$5,500 minimum to \$11,000 maximum
 - PLUS:
 - Government Court Costs
 - Attorney Fees
 - Liable for seven years of activity
- New Special Statute- \$50,000/kickback

So What is the Problem?

Is There a Corruption of Medical Judgment?

The Patient

- 2004 Vioxx Withdrawal
- 2005 Bextra Sales Suspended
 - 2005 ??
 - 2006 ??

The Patient

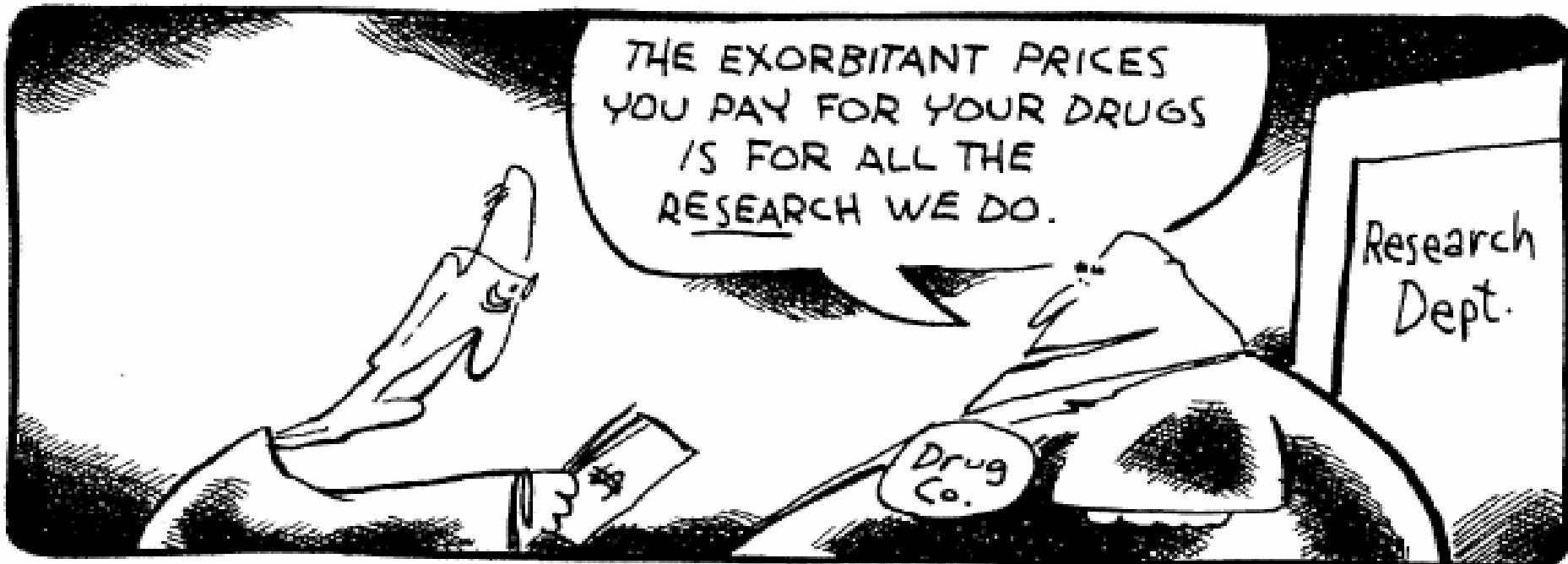
Propulsid

- July 2005 – Senate Finance Committee inquiry into whether Pharma co. used educational grants to promote the pediatric use of its' heartburn medicine in the 1990's.
- Pharma co. paid for a physician's book that recommended Propulsid's use in children and gave grants to organizations that favored the use.
- Propulsid withdrawn from market in 2000 after a reported 80 heart related deaths & 341 injuries.

Senate Investigation

Committee Chairman:

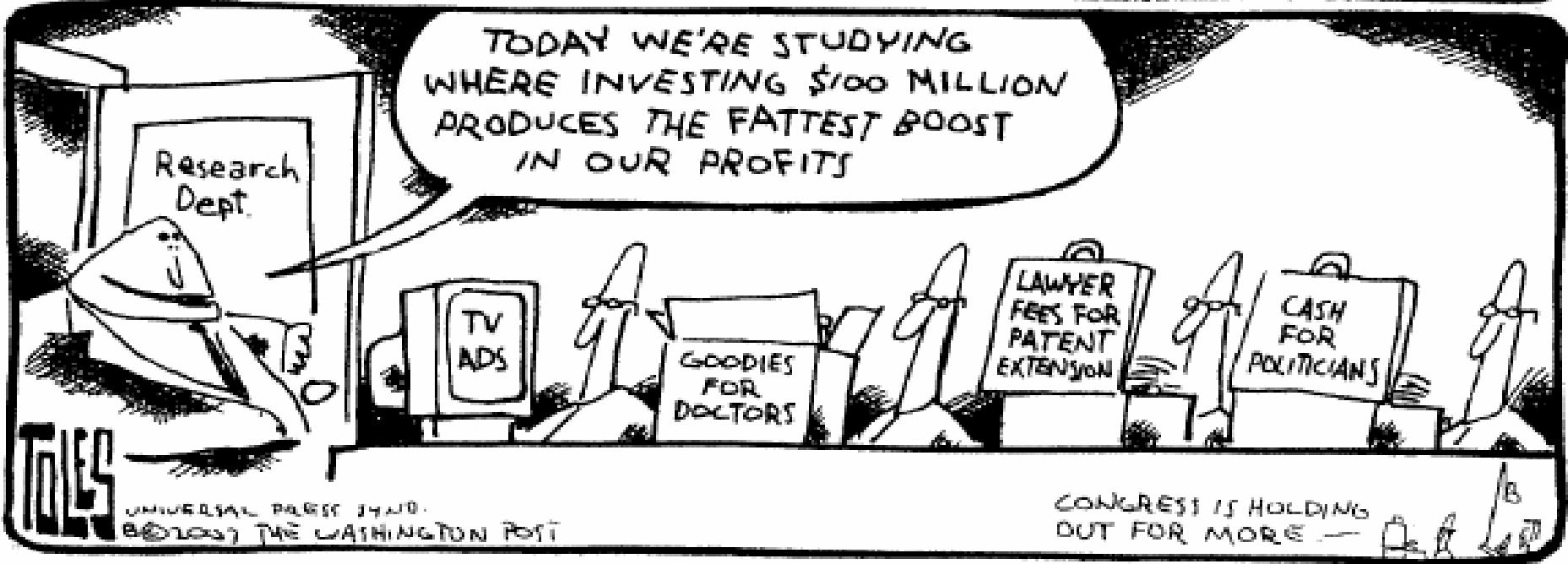
“how do pharmaceutical companies sometimes use physician education seminars and research grants to discuss using drugs to treat conditions beyond those approved by the FDA.”



THE EXORBITANT PRICES
YOU PAY FOR YOUR DRUGS
IS FOR ALL THE
RESEARCH WE DO.

Research
Dept.

Drug
Co.



TODAY WE'RE STUDYING
WHERE INVESTING \$100 MILLION
PRODUCES THE FATTEST BOOST
IN OUR PROFITS

Research
Dept.

TV
ADS

GOODIES
FOR
DOCTORS

LAWYER
FEES FOR
PATENT
EXTENSION

CASH
FOR
POLITICIANS

TOLES

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CONGRESS IS HOLDING
OUT FOR MORE —

Recent Pharmaceutical Settlements

- TAP Pharmaceuticals - \$875 Million
- Bayer Pharmaceuticals - \$ 257 Million
- GlaxoSmithKline Pharmaceuticals – \$ 87 Million

More Settlements

- Schering Plough - \$350 Million
- AstraZeneca - \$355 Million
- Abbott Laboratories - \$600 Million
- Others in discussion or in the pipeline

TAP SETTLEMENT

- Fraudulent drug pricing and marketing conduct with regard to Lupron, a drug sold by TAP used to treat patients with prostate cancer.
- Directed Docs to bill Medicare for free Lupron samples
- Offered Docs large educational grants to switch patients to Lupron from a competing prostate cancer drug.

TAP Pharmaceutical

Largest Healthcare Fraud Settlement

\$ 875 Million

\$ 290 Million Criminal Fine

\$ 585 Million Civil Penalties

Whistleblower case, payments received:

TAP former VP of Sales - \$ 77 Million

Urologist @ Tufts - \$ 17 Million

TAP SETTLEMENT

Corporate Integrity Agreement is one of the most comprehensive ever negotiated by the OIG:

For example: (1) the government will oversee all the sales and marketing practices (2) require Lupron to be billed to Medicare & Medicaid on the average sale price instead of the average wholesale price (3) CCO must report to the OIG

http://oig.hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf

TAP SETTLEMENT

TAP agreed to cooperate fully with the ongoing federal grand jury investigations of its former officers and employees

Eleven (11) former executives & 5 Physicians were indicted and charged with conspiracy to pay kickbacks, fraudulent billing, offering gifts/inducements in exchange for referrals.. Four (4) physicians pleaded guilty

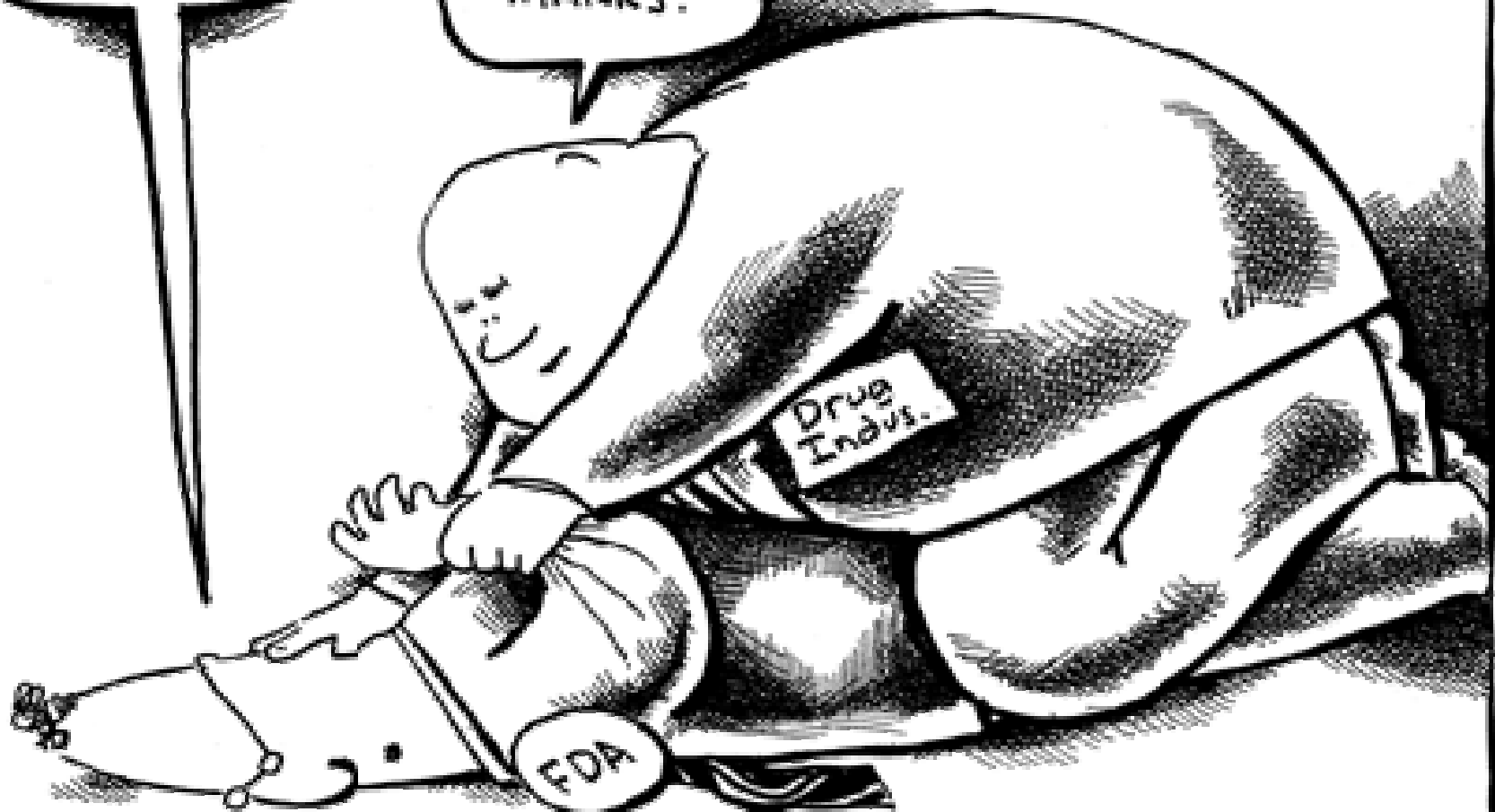
Courts have ruled in favor of the TAP Employees, which was a defeat for government prosecutors

There are many more investigations underway

- Physicians/Hospitals will likely get caught in the fire of these investigations.
- NIH Questions

PUSH DOWN
WHILE
TURNING.

THANKS.



TUES

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Bret Bissey - Conflicts of Interest I'LL TAKE THAT AS APPROVAL

Why are Inducements such an Important Topic?

- Review of Relevant Documents
 - Anti-Kickback Statute
 - OIG Compliance Guidance for Pharmaceutical Manufacturers
 - AMA Guidelines
 - PhRMA Guidelines
 - Settlements, Investigations

- **Conflicts → ? Integrity of your Decisions**

Anti-Kickback Statute

- Federal Criminal Law
- Criminal Penalties against any individual or entity that:

knowingly and willingly offers or pays any remuneration directly or indirectly, overtly or covertly, in cash or in kind to induce such person to:

Anti-Kickback (cont)

- To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be in whole or in part under a Federal Health Program, or
- to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be in whole or in part under a Federal Health Program

Anti-Kickback (cont)

- Applies to Medicare, Medicaid and other Federal Program Payors
- **Applies to Both Sides of a Transaction** (Physician and Hospital/Vendor)
- Penalties can include Prison, fines, exclusion from Medicare
- New Special Statute- \$50,000/kickback
- Standard of Proof
 - Beyond a reasonable doubt, knowing and willful violation, evidence of intent

NJ Orthopedic Surgeons

- Fraud in the Inducement
 - Government looking for cases where treatments are being made in which the ordering physician may have been induced
 - Violation of Anti-kickback statute (federal law)
- March, 2005 -- NJ Attorney General subpoena of 5 hip and knee implant manufacturers – consulting and service contracts with orthopedic surgeons

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

- Issued April 28, 2003

<http://oig.hhs.gov/authorities/docs/03/050503FRCPPGPharmac.pdf>

- But not the first document that raises suspicion about relationships between providers and vendors

American Medical Association Ethical Statement on Gifts

August, 2001 (last update)

- www.ama-assn.org/ama/pub/category/8484.html
- Published Ethical Opinions/Guidelines on Gifts to Physicians from Industry
- “#1 - Any gift accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value...”

American Medical Association (cont)

- “growing concern about certain gifts from industry to physicians”
- “some gifts that reflect customary practices of the industry may not be consistent with the Principles of Medical Ethics..”
- “gifts of minimal value are permissible..”

Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines

- July 1, 2002 (Voluntary for Industry)
- www.phrma.org/publications/2002-04-19.391.pdf
- “Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine.”
- Meals may be offered that are modest and conducive to the educational venue. HC professionals spouse or guest is not appropriate. Take out meals without the company rep being present is not appropriate.

Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines (cont)

- 3rd Party meetings, financial support should be given to the sponsor, not attendee
- No travel, lodging to non-faculty
- Consultants, OK if reasonably compensated (fair market value) and it is for bona fide work

Office of Inspector General Guidance

- Covers many different topics for the Pharmaceutical Industry
- OIG has been analyzing the pharmaceutical and device industry for years
- Yes, the device industry is implicitly covered under this guidance

What is it all about?

- Conflicts of Interest
- Fair Market Value

Potentially Problematic Relationships per the OIG

- **Switching Arrangements** – physicians offered \$\$ or benefits to change a patients' Rx. Implicates anti-kickback statute.
- **Consulting & Advisory Payments** – If fair market value for bona fide services probably no problem, but compensating physicians as “consultants” to attend meetings or conferences is “suspect.”

Potentially Problematic Relationships per the OIG

- **Payments for Detailing** – compensation to physician for time spent listening to pharmaceutical sales representatives. Paying physician for time spent to access web sites to view or listen to marketing information or perform “research.” “These activities are highly suspect.”

Potentially Problematic Relationships per the OIG

- **Business Courtesies and Other Gratuities** – Entertainment, travel, meal and gifts may be a violation. The guidance suggests that physicians consult the PhRMA Code on Interactions with HC professionals to minimize potential risks.
 - Keep in mind, are these situations a conflict of interest and/or fair market value??? What is reasonable?? Ethical and rational judgment needed.

Potentially Problematic Relationships per the OIG

- **Educational and Research Funding** – Payments to physicians should be fair market value for legitimate, reasonable and necessary services. Research contracts that originate through the sales or marketing function may be suspect.

How do you make sure you are compliant with the Pharma Guidance?

- Ask yourself
 - Is this a conflict of interest?
 - Am I being paid fair market value?
 - Would disclosure of this relationship hurt your reputation?
- Ask a Colleague
 - Does this seem ok to you?

Other Tips

- Add the OIG Pharmaceutical Guidance components to your compliance plan to state that you will follow this guidance
- Example: 13 physician practice with 12 ethical and honest physicians, 1 physician violates this ethical practice and is caught.
 - Does one bad apple spoil all 12???
 - I would not want to be one of the 12, I'd rather disassociate that 1 physician from the practice by my own internal policies.

What might Prosecutors Analyze?

- **Did the corruption of Medical Judgment Occur??**
 - all medical decisions should be made in the best interest of the patient not for the financial interest of a provider

There are names for some of the suspicious programs

- Dine and Dash
 - Gas and Go
 - Pay to Dine
- How about:
 - Entertain and prescribe
 - Compensate to Listen

How do you Protect Yourself?

- Awareness of Relationships
- Manage Relationships
- Analyze Relationships

- Ignorance of Relationships is not a good defense.

Opportunity Cost

- Technology is available to assist
- One Example → Contract Management Services
 - Assist with Conflicts of Interest, Stark Issues, Responding to Investigations, HIPAA, etc...
 - Validate by reading the latest OIG Guidance for Hospitals on Contracts...
- Be open minded to review technology

Conflicts of Interest / Ethical Statements

- ❏ Avoid any activity or business transaction which conflicts with your institution's best interests.
- ❏ All decisions should always be in the best interest of the patient.

Conflict of Interest Disclosure Process

Suggestions to be Compliant

- Keep documentation that the contracted work is necessary and at fair market value
- If questions arise, and an investigation occurs – cooperate & have documentation
- If it seems too good, it probably is
- Don't follow the crowd, be suspicious
- Be knowledgeable about what investigators are analyzing

How do you Protect Yourself?

- Conflict of Interest Policies
- Conflict of Interest Disclosure Policy with consequences
- Educate, Educate, Educate
- Audit, Audit, Audit
- Monitor, Monitor, Monitor
- Document, Document, Document

Your Conflict of Interest Policy

- What is the Standard at your institution/practice?
- If an investigation “breaks out” can you justify your standard to :
 - Patients
 - Press
 - Investigators
 - Peers

Your Conflict of Interest Policy

- Can You Comply with Your Policy?
- Example: Are you really worried about a \$25 or \$50 gift from a vendor?
 - Some people are
 - Others want to focus on what they can manage
- How do you get organized to manage

Conflict of Interest Policies

- What are acceptable behavior/relationships?
- Establish specific limits for goods/services
- Provide examples of conflicts
- Require disclosure of anything above \$ limits
- Consequences of failure to disclose
- Consider incorporating standards into the Medical Staff Bylaws
- Review and act upon disclosures

Conflict of Interest Disclosure

- Written document which must be completed and certified even if there is no disclosure (how)
- Minimum Annually Capture new hires
- Require updates if anything changes or becomes new
- Assure confidentiality with handling of documents
- Looking for relationships *\$\$\$* which may potentially be problematic
- Refer to your policies at the beginning of the document

Education, Audits and Monitoring

- Compliance Officer must constantly remind your colleagues about this risk/threat. Be creative in how you tell the story.
- Structure audits with certain vendors
- Contracts with vendors should include clauses that they must notify you of any relationships with your employees that might impact this relationship
- Monitor communications if you have suspicion
 - Make sure policy allows surveillance

Closing Thought - A Couple of Defenses Not to Use

- I can not find the Contract
- Everybody is doing it
 - Do not fall for this.
 - Was Sammy Sosa the only one with a corked bat??
- I did not understand the rules
 - You must be educated on this topic.