





# Department of Justice Prosecuting HIPAA Violations

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# Enforcement Issues

- What was the core evil:
  - ◆ Corruption of medical judgment
  - ◆ Cheating on best price
  - ◆ Buying patient privacy information
- What impact did that “core evil” have on exercise of medical judgments? Payment for health care? Patient choice of treatments? Cost to patients? Invasion of patient privacy?
- What crimes were committed?
  - ◆ Anti-kick back statute
  - ◆ False claims, cheating on Medicaid rebates
  - ◆ Inflation of costs and prices to cover kickbacks

# HIPAA Patient Privacy

- **Section 1320d-6 provides that a person who “knowingly” and “in violation of this part”:**
  - ◆ **(1) uses or causes to be used a unique health identifier;**
  - ◆ **(2) obtains individually identifiable health information relating to an individual;**  
or
  - ◆ **(3) discloses individually identifiable health information to another person**
- **shall be punished depending on three levels of intent.**

# Levels of intent:

- **If the offense is committed**
  - ◆ **without any additional intent,**
  - ◆ **Misdemeanor.**
- **If the offense is committed**
  - ◆ **“under false pretenses”,**
  - ◆ **Felony, \$100,000 fine and 5 years imprisonment.**
- **If the offense is committed:**
  - ◆ **“with intent to sell, transfer or use individually identifiable health information for commercial advantage, personal gain, or malicious harm”**
  - ◆ **Felony, \$250,000 fine, 10 years imprisonment.**

# Will there be prosecutions?

- **Unlikely to be misdemeanor prosecutions for “accidental” “incidental” or “solitary” disclosures**
- **Systemic problems may get addressed: a covered entity that willfully decides to ignore the rules because doing so will affect profit margins**
- **Key area of likely interest for prosecutors: trading/selling individually identifiable health information for financial gain**

# Implications for marketing

- **Before April 2003, marketing activities routinely involved disclosure of patient identifying information**
  - ◆ **Visit to doctor's office**
  - ◆ **Grand rounds**
  - ◆ **Tracking new patient starts**
  - ◆ **Access to restricted areas**
  - ◆ **Preceptorship payment to a doctor to learn his practice**
  - ◆ **Attendance at screening events**

# Are these activities legal?

- **Depends.**
- **Does the doctor have each patient's consent to disclose patient identifying information?**
- Covered entities may find it impracticable to craft an authorization for each patient that would cover disclosure of information to a specifically identified vendor's sales employees or classes of such persons.



# Rules were strengthened for marketing activities

- [T]he Department has added new language to the definition of “marketing” to close what commentators perceived as a loophole that a covered entity could sell protected health information to another company for the marketing of that company’s products or services. For example, many were concerned that a pharmaceutical company could pay a provider for a list of patients with a particular condition or taking a particular medication and then use that list to market its own drug products directly to those patients.
  - 11067 Fed.Reg. 53182, 53187 (August 14, 2002).

# Sentencing for Health Care Crimes

- Key determinants: the greater of the:
  - ◆ loss caused
  - ◆ Gain to defendants
- In health care offenses, losses/gains accrue very quickly
- Likely key determinant for HIPAA privacy crimes: **financial gain** intended from misuse of patient protected health information

# United States v. Thurston

- Crime 1988: adding an **\$18** ferritin test to an **\$18** panel, to offset a Medicare rate reduction
- Only Medicare was billed: loss over five years: **\$16,000,000**. Gain to Thurston: salary, bonus
- Indicted in January 1998
- Tried, convicted, 3 week trial, Nov-Dec 2001
- Sentenced to only **3 months jail** in June 2002
- Government appeal
- Conviction affirmed, sentence reversed, Feb 2004
- New sentence: **five years imprisonment**

# Pharmaceutical Industry Cases

- **\$885 million**, \$290 million criminal, TAP
- **\$600 million**, \$200 million criminal, Abbott
- **\$355 million**, \$63.9 million criminal, Astra Zeneca
- **\$257 million**, \$6 million criminal, Bayer A.G.
- **\$87.6 million**, GlaxoSmithKline
- **\$49 million**, Pfizer
- **\$18.5 million**, Dey Laboratories
- **\$14 million**, Bayer A.G.

**Total since 2000: \$2,266,500,000**  
**Criminal Fines: \$593,900,000**

- **No other sector of the health care industry has ever paid similar amounts in health care fraud investigations in so short a time**

# Whistleblowers

<u>Case</u>	<u>Type of Case</u>	<u>Whistleblower Share</u>
<b>TAP</b>	Drug samples Inducements	<b>\$95,000,000</b> , split \$78,000,000 and \$17,000,000
<b>Astra Zeneca</b>	Drug samples Marketing misconduct	<b>\$47,500,000</b> , whistleblower in TAP
<b>Dey, Inc.</b>	False billing charges to Medicaid in Texas	<b>\$1,841,400</b>
<b>Bayer GSK</b>	“Lick and Stick” re-labeling	<b>\$34,000,000</b>
<b>Columbia/HCA 9 FCA Cases</b>	Kickbacks False billing Billing for unallowable costs	<b>\$100,000,000, \$41,500,000, \$5,000,000, \$2,990,000, \$680,000, \$837,500, \$116,500, \$405,000.</b>

**\$330,000,000**

paid to whistleblowers  
for reporting fraud  
by  
just **six** companies