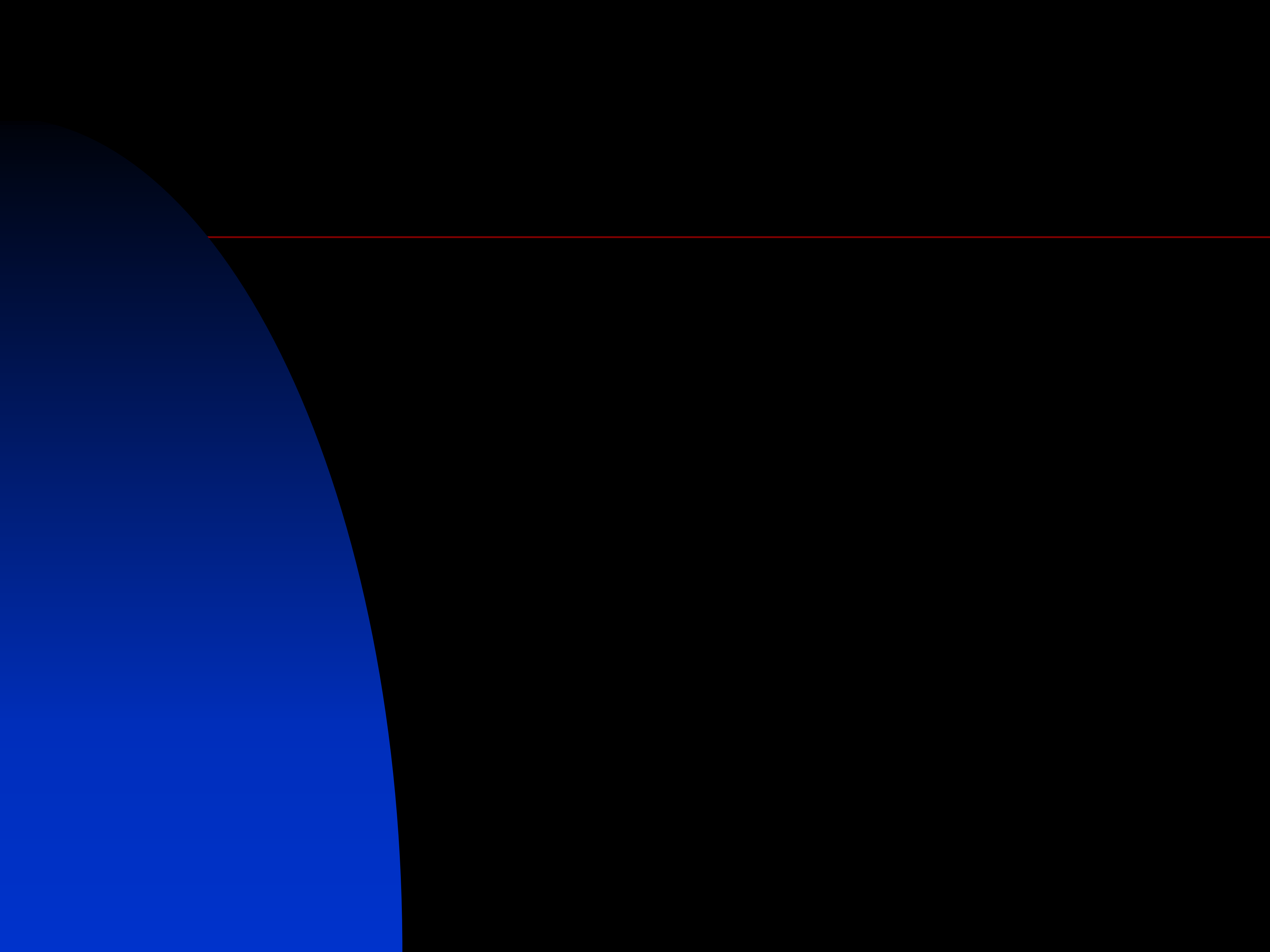

Department of Justice Investigations and the Pharmaceutical Industry

Michael Loucks

Health Care Fraud Chief

District of Massachusetts

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**

FRIDAY, APRIL 11, 2003

THE BOSTON GLOBE

WAR IN IRAQ RESHAPING THE GOVERNMENT

The World A39

Information minister finds a rare status

CAMP SAYLIYAH, Qatar — He called US invaders "louts," "hooligans," "dogs," "mercenaries," and "infidels." "They are the superpower of villains," he said. "They are the superpower of Al Capone."

Mohammed Saeed al-Sahaf, Iraqi's information minister, was unperturbed Sunday as smoke from US tank fire rose over the Iraqi capital and US soldiers tried out Saddam Hussein's palace armchairs.

"They are committing suicide on the gates of Baghdad," he told reporters clustered outside the Palestine Hotel. "I would encourage them to commit more suicide."

As Saddam Hussein was falling from his rule over Baghdad Wednesday, it was surprising not to see Sahaf show up to deny it. His jaunty beret, his air of enthusiasm, and especially his intricate verbal riffs promising to "grill their stomachs in hell" had won him rock-star status among some Arabs.

Fans have even created a website: www.welovetheiraqi-informationminister.com. On Wednesday, the site listed as its quote of the day Sahaf's call for US soldiers to "surrender or be burned in their tanks."

Sahaf, 63, was demoted to his current (former?) job from the position of foreign minister. But as the chief PR man for Saddam Hussein, the English literature major seemed to have found his calling.

US Marine Captain Stewart Upton, whose phone at US Central Command here lit up every day around 7 p.m. with reporters asking him about Sahaf's claim that Iraq had shot down 196 US missiles or five Apache helicopters, didn't miss him yesterday. But others are rooting for him to resurface. Said one US cameraman, "He should be a publicist for a pharmaceutical company."

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ANNE BARNARD

Enforcement is Pro-Business

- 2002, Average Cost, employee health benefits = $5,645 *per employee*
  - A firm with 1,000 employees pays > $5.6 million
  - Growth 2001: 11.2%; 2002: 14.7%
  - US per capita health care expenditures, 2002 = $5,037. By 2010: $8,368
- Baby Boomers hit 65 starting in 2010
  - Medicare Program expenditures will double in next six years, then double again rapidly
  - Private sector growth will be similar

Pharmaceutical Costs

- Retail Pharmaceutical Expenditures:
  - 1997, about $80 billion dollars
  - 2001, about 150 billion dollars
- Drugs, in 1990, were a tiny fraction of the Medicare Program budget
  - Medicare now spends in the billions
- How big is the fraud problem?
  - In the 1990s, Medicare paid TAP about 2.7 billion
  - TAP paid, in fines, penalties, nearly $900 million

Sources of Cases

- Anonymous calls
- Audits
- Old fashioned leg work
- Whistleblower suits

Some facts on whistleblowers

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

$330,000,000

paid to whistleblowers
for reporting fraud
by
just five companies

Four main kinds of HCF cases

- Anti-kickback statute prosecutions
- False claims cases, criminal and civil
- Food, Drug and Cosmetic Act crimes
- Conspiring to defraud an agency by interfering with its lawful functions through trickery, fraud and deceit

Matters we are now working:

- Significant number of anti-kickback cases:
  - These cases present at their core the issue of corruption of medical judgment
  - Who controls the prescribing decision:
    - Doctor?
    - HMO management?
    - Pharmaceutical Benefit Manager?
    - Hospital formulary
- As control over prescribing decision shifts, so do the illicit payments
  - Key participant in these crimes is the provider

- An increase in allegations of FDA violations
  - Off label promotion
- Investigations involving gamesmanship with the payment rules:
  - Investigations focused on tricky, deceitful conduct designed to defraud an agency by keeping it from doing its job in administering a government program
- Best price issues

42 U.S.C. Section 1320a-7b: The Anti-Kickback Statute

- A payer can be guilty of an "illegal remuneration" in violation of 1320a-7b(b)(2) if he:
  - (1) knowingly and willfully
  - (2) offers or pays
  - (3) any remuneration, including any kickback, bribe or rebate,
  - (4) directly or indirectly, overtly or covertly, in cash or in kind
  - (5) to any person to induce that person

Payer crime continued

- to do either of the following two things:
  - (1) to refer an individual … for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program; or
  - (2) to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good facility, service or item for which payment may be made in whole or in part under a Federal health care program.

Kickback statute comments:

- An offer to pay is a crime.
- Provider need never in fact get the money.
- Cost to system or loss caused by kickback is not relevant.
- Provider who solicits payment for a referral commits the crime even if the demand is rejected

How is a kickback crime analyzed

- Did something of value get offered, requested, exchange hands? If so, why? What was the true purpose?
- If so, was the conduct willful?
  - Did the provider's treatment pattern change?
  - Were patients switched from one treatment modality to another because of the kickback?
  - If patients were switched, were they consulted? Were they told about the inducement?
  - Did the parties know about the anti-kickback statute?
- If so, is there a safe harbor?
- If so, was some or all of the expected/desired business paid for by a federal health care program?

The any purpose test

- Kickback payments are often disguised as something else:
  - As payments for services rendered
    - So-called Consultant fees
    - Travel reimbursement
  - As payments for another product (or as reductions in price on another product)
- Legal test: if one purpose of the payment is to induce referrals, the statute is violated

Expressions of Intent

- "The Lahues told University that if the hospital wasn't interested in increasing the salary, they … would no longer be putting patients in our institution."
- "Dr. Lahue told Mr. McGrath that BVMG feels they have value in the 2,000 nursing home beds they control. They wish to work out any arrangement with Health Midwest that pays them for this value."
  - **United States v. Anderson, 85 F.Supp.2d 1047, 1054, 1059 (D.Kan. 1999), rev'd in part in United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000).**

Quid Pro Quo

- “For every sample you give me, I’ll switch one patient to your drug.”
- “I’ve always been a loyal customer. Co. X just offered to send me to the AMA annual meeting if I start using their drug. You know I really don’t want to do that; can you help me out here?
- “Company X has always given us money for our fellowship program. If you can help us out, I’m sure the P & T committee will take that into account.”

Kickbacks and Best Price Crimes

- Medicaid best price agreements:
  - Price sold to the Medicaid program = best price sold to any customer in the relevant quarter
- Cheating on best price typically involves moving a price concession off invoice
  - Becomes a hidden discount
  - Hidden discount becomes a kickback

Kickbacks and Best Price Crimes

- “Having to give Medicaid the best price means every time I drop my price for someone else, I have to send the government some money – the rebate – and that “hurts” my bottom line.”
- “This provider tells me XYZ Pharma Co. is doing something for him to get the price down: I could lose this business if I don’t play ball.”

- “Isn’t there some way –
  - coupons, nominal goods, golf tournaments, free golf balls, free drug, cash paid back off invoice, trips to resorts, sales swaps, product swaps, price discounts on other products, repacking the product with a new label –

  that I can lower my price and keep the business?”

Off Label Promotion

- Physician prescription of a product off-label is lawful
- Drug company must obtain FDA approval to sell drug:
  - Must demonstrate drug is safe and effective for intended use
  - Drug must contain labeling reflecting, among other things, conditions of use

Factors relevant to prosecution

- What is the total marketplace for the approved uses?
- Is the company targeting doctors who do **not** treat persons with the intended medical issues?
  - Does it have sales budgets for non-approved uses?
  - Are employees paid bonuses for sales for non-approved uses?
- Did company seek FDA approval for other uses and not get it?

Relevant Factors

- Did the company choose not to seek FDA approval?   Why not?
  - To protect a future drug from generic competition?
  - Because data does not demonstrate product is safe and effective?
- If company is using literature to support unapproved uses, does it claim the product is safe and effective for those uses?
- Does it employ consultants to push off label uses?
- Does it incent customers to prescribe off label?

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.

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 apply to drug companies

- [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).

Defenses that are not persuasive

- Everyone else is doing it.
  - That may not be true.
  - Even if they are, so what.
- Consider TAP, Zeneca
  - Both companies gave samples, money, trips, consulting to steal business from each other
  - Each accused the other of violating the law
  - TAP pled guilty, paid $885 million
  - Zeneca pled guilty, paid $355 million
- Government recovery: **$1.24 billion** for crimes involving **2** drugs, **1** disease

Defenses that are not persuasive

- I didn't understand the rules.
  - "Section 1320a-7b is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct. Indeed, the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal; compared to the licensing provisions that the *Bryan* court considered, kickbacks are clearly *malum in se*, rather than *malum prohibitum*."

Defenses, cont.

- Questions we ask when this defense is raised:
  - Did the provider or the drug company ask the agency what it thought about the clever new pricing scheme? Did they seek legal advice?
  - If the program was so confusing, why did the company and its best customer have to come up with some off-invoice way to reduce price?

Key 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

Key enforcement issues, cont.

- Was the evil isolated: a few corrupt employees or a corporate-wide program?
  - If the latter, was the culture of corruption unique to company? was it industry wide?
  - If industry wide, does that somehow excuse the conduct?

- Whose judgment was corrupted: single doctor, core member of P & T committee of institutional provider?
- What was the agency’s regulatory history? Did government conduct provide defenses?
  - Was core evil invited? Tolerated? Known? Encouraged?
- Was there any trafficking in patient protected information, without patient consent?