

A world map is visible in the background, rendered in a light blue color against a dark blue background. A white grid is overlaid on the map, consisting of three vertical columns and three horizontal rows. The text is centered within the grid.

# Sales and Marketing in the Pharmaceutical Industry: At the Vortex of the Perfect Legal Storm

Paul E. Kalb, M.D., J.D.

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# Sales & Marketing Practices Under Intense Scrutiny

June 1995	Caremark - \$161 million
May 1999	Genentech - \$50 million
January 2001	Bayer - \$14 million
September 2001	TAP - \$870+ million
October 2002	Pfizer - \$49 million
April 2003	Bayer - \$257 million GlaxoSmithKline - \$90 million
June 2003	AstraZeneca - \$355 million Guidant - \$92.4 million Dey, Inc. - \$18 million
July 2003	Abbott Laboratories - \$600 million
May 2004	Parke-Davis - \$427 million

# The Perfect Storm

Cases at the vortex of six statutory schemes:

1. False Claims Act
2. Consumer Protection Statutes
3. Anti-Kickback Statute
4. Food, Drug and Cosmetic Act
5. Product Liability Laws
6. Social Security Act

# 1. False Claims Act

- Thou shalt not knowingly submit, or cause the submission of, false claims to the government
  - “Knowing” includes reckless disregard
  - Treble damages plus up to \$11,000/false claim
  - “*Qui tam*” (whistleblower) provisions allow private individuals to bring claims “on behalf of” the government
- State law analogues

## 2. Consumer Protection Statutes

- Generally prohibit unlawful, unfair or deceptive trade practices
- Cal. Code §17200
  - Private Attorney General provision
  - No injury requirement

### 3. Anti-Kickback Statute

- Thou shalt not knowingly and willfully offer or give any remuneration intended to induce the purchase, prescription, or recommendation of drugs
  - “Remuneration” is broadly defined
  - Statute is reciprocal
  - Numerous exceptions/safe-harbors - e.g., bona fide services, discounts, employees, GPO administrative fees, certain managed care arrangements
- State law analogues

## 4. FDCA

**Misbranding:** A drug is “misbranded” if “its labeling is false or misleading in any particular,” or “its labeling” does not “bear[] adequate directions for use.”

**New Drug:** “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of [a new drug] application...is effective with respect to such drug.”

## 5. Product Liability Laws

- Provide causes of action for patients who suffer injury, generally as a result of negligence or other improper conduct of some sort
  - Prescription drugs: Learned Intermediary Defense

## 6. Social Security Act

- Among many other substantive provisions:
  - Requires HHS OIG mandatorily to exclude entities from participation in federal health care programs upon conviction of certain crimes
  - Authorizes HHS permissively to exclude entities under other circumstances

# Application to Sales & Marketing Practices

	Improper Inducements	Off-Label Promotion	“Fraud-on- the-FDA” NDAs, 510ks, AERs, GMPs, Research Conflicts?
FCA			
17200			
Product Liability			

# The Hazards of Parallel Proceedings

- The problem of synergy:
  - The “best” fraud and abuse case involves an injured patient

“Where a medically inappropriate drug-switching program ... results in serious injury or death to a health plan beneficiary, there will be substantial prosecutive interest ... under a fraud theory.”

- James Sheehan, Assistant U.S. Attorney, Philadelphia
  - Evidence of illegal (particularly criminal) conduct bolsters any product liability claim

# The Hazards of Parallel Proceedings

- Criminal and civil
  - Great government leverage
  - Fifth Amendment issues
    - Adverse inference in civil proceedings
  - Coordination of separate counsel

# From “Legal” Framework to “Marketing” Framework

- Is there a violation?
  - fraud and abuse
  - off-label
  - product liability
  - privacy
  - antitrust
  - securities

- Has the company injured a person?
  - person's privacy
  - government program ?
  - competitor
  - investor

Paul E. Kalb  
Sidley Austin Brown & Wood LLP  
(202) 736-8050  
pkalb@sidley.com