

ARNOLD & PORTER LLP

**How the Congress, the Press and  
the Prosecution Community  
Have Contributed and Responded  
to the Debate About Drug Safety**

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## CAVEAT

The law places ethical restrictions on my ability to discuss matters pending in the Office of the Inspector General while I was the Acting Inspector General. In addition, I cannot discuss any pending investigations.

# The Congress

## The Senate Finance Committee

- Recent shift from traditional healthcare fraud to drug safety
  - Anti-depressant abuse in children
  - Vioxx debate
- “Safety of the public . . . has to have priority over the profits of drug companies”  
—Senator Charles E. Grassley
- Role of whistleblowers
  - Most recent pharmaceutical prosecutions under the Federal False Claims Act brought by whistleblowers
  - Relationship of whistleblowers to the Senate Finance Committee

## Continued Involvement of the Senate Finance Committee

- National Institutes of Health and Ethics Issues
- Alleged conflicts of interest on FDA advisory panel evaluation of Cox-Z inhibitors

## The Senate Committee on Health, Education, Labor and Pensions

- Hearing on March 3, 2005
- Increasing FDA authority
  - Demand safety-related changes in drug labels
  - Require additional clinical studies

## Other Congressional Issues

- Increased sensitivity to drug prices
- Drug reimportation—changing response over time
- Conflict between safety and price concerns

## Observations of the Senate Finance Committee

- Close relationship while Acting Inspector General
- Identification with whistleblowers and prosecutors
- Transparency issues
  - Clinical trials
  - Justification for settlement agreements



# THE PRESS

# The New York Times

November 22, 2002

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## MADISON AVENUE HAS GROWING ROLE IN THE BUSINESS OF DRUG RESEARCH

- Advertising companies investing millions of dollars in companies that perform clinical trials
- OIG guidance to the pharmaceutical industry—separate pharmaceutical grants from the marketing department
- Concern about compromising research and data integrity
  - Inspector General guidance and PhRMA code

## **DRUG FIRMS SAY SECRECY FOSTERED CREDIBILITY “CRISIS”; IN HOUSE TESTIMONY, INDUSTRY OFFICIALS ADMIT FAILING TO PUBLISH STUDIES ON ANTIDEPRESSANTS AND CHILD SUICIDAL BEHAVIOR CAUSED A PUBLIC BREACH**

- Three studies with negative findings about antidepressant use in children not published
- Children more likely to have suicidal thoughts or behavior on antidepressants
- Admission of compromised integrity

# Los Angeles Times

February 1, 2005

## **NIH TO BAN DEALS WITH DRUG FIRMS; FEDERAL RESEARCHERS WILL NO LONGER BE ABLE TO ACCEPT FEES TO CONSULT FOR COMPANIES, OFFICIALS SAY. THE LUCRATIVE PACTS HAVE SPARKED ETHICS PROBES.**

- LA Times investigative reporter broke NIH story in 2003
- Four congressional hearings into conflict of interest at NIH convened in 2004
- Loss of public trust not only in government officials, but also pharmaceutical industry
- Nondisclosure of payments from pharmaceutical companies
  - Transparency problem

# The New York Times

February 25, 2005

## 10 VOTERS ON PANEL BACKING PAIN PILLS HAD INDUSTRY TIES

- If the ten advisors who had consulted with drug companies had not voted, Bextra and Vioxx would not have been returned to the market
- Need for transparency
- Followed by report on World News Tonight on 2/25/2005

# Chicago Tribune

February 26, 2005

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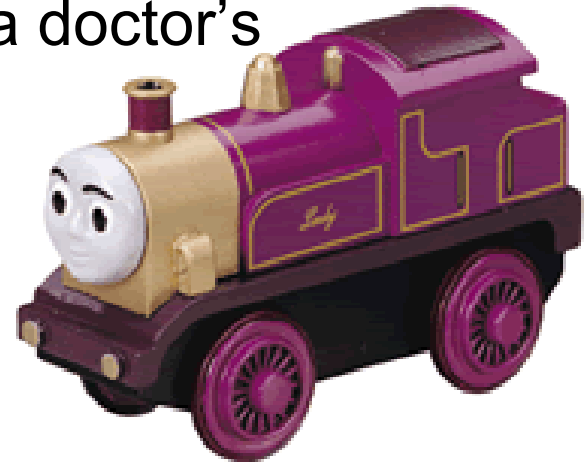
## **DRUGS GET GOOD RATINGS, BUT DRUGMAKERS LESS SO; INDUSTRY TARGETS PROFIT PRIMARILY, AMERICANS THINK**

- Large majority of people acknowledge the benefits of drugs
  - Drugs are not the new tobacco
- Public does not believe research and development argument (81%)

# Response of Law Enforcement

## Aggressive Prosecution

- Neurontin Case
  - Ghost-written articles, trips, sham “educational” session and grants
  - Example of the type of case that law enforcement likes—potentially high damages and egregious conduct the could improperly influence a doctor’s judgment
- Thomas the Tank Engine





## OTHER SIDE OF THE COIN



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July 15, 2004

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### TAP MANAGERS ACQUITTED; DRUG MAKER HAD ALREADY PLEADED GUILTY

- Difference between individual and corporate liability

**The Boston Globe**

July 15, 2004

**All acquitted in drug kickbacks case jury deals a blow to U.S. prosecutors**

# The New York Times

March 4, 2005

## DRUG MAKERS ARE STILL GIVING GIFTS TO DOCTORS, FDA OFFICIALS TELL SENATORS

- FDA claims that drug companies still spend more on marketing than they do on research and development
  - Inspector General priority remains the investigation of kickbacks
  - Justice Department uses the False Claims Act to address violations of the Anti-Kickback statute

# The New York Times

June 3, 2004

## **SPITZER SUES A DRUG MAKER, SAYING IT HID NEGATIVE DATA**

- Data concerning negative clinical studies
- Theory of fraud in failing to tell doctors about negative studies
  - Violation of New York consumer protection laws
  - Marketing data inconsistent with clinical trials

# Chicago Tribune

March 4, 2005

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## PRESSURE BUILDS TO CURB ADVERTISING FOR DRUGS

- Blame the pharmaceutical companies not the doctors
- Accounting for increased prescription drug use with direct to consumer advertising
- Fundamental questions
  - Does advertising lead to overutilization?
  - Does advertising understate the risk?

## MOVE TOWARDS HEIGHTENED LEGAL RESTRICTIONS ON PHARMACEUTICAL AND DEVICE MANUFACTURERS

- “Simple” health care fraud case
  - Falsifying documents, services not provided, providing services that were not medically necessary
  - Introduction of corporate integrity agreements
- “Complex” health care fraud case
  - Recent pricing
  - More onerous corporate integrity agreements
- Inspector General Guidance to the Pharmaceutical Industry
- Self-policing—the PhRMA and AdvMed Codes
- California law 1765—legislature catches up with law enforcement