State Attorney General Investigations and Litigation

Barry H. Boise | November 3, 2011

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The State Compliance Environment

- Increasing efforts by states to regulate:
  - Advertising and promotional spend limits/disclosures
  - Gift reporting and/or limits
  - Sales representative registration
  - Efforts to limit data-mining and Sorrell decision
  - Requirements to adopt Code of Conduct
- State Medicaid Fraud Control Units
  - Increasing state FCA legislation and incentives
  - Coordination with DOJ
- Consumer protection laws

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State Regulation and Enforcement Landscape

- Consumer protection actions used to enforce FDCA and PhRMA Code
- State attorneys general
- Plaintiffs' personal injury bar
- Regulation through consent decrees
- Compliance implications

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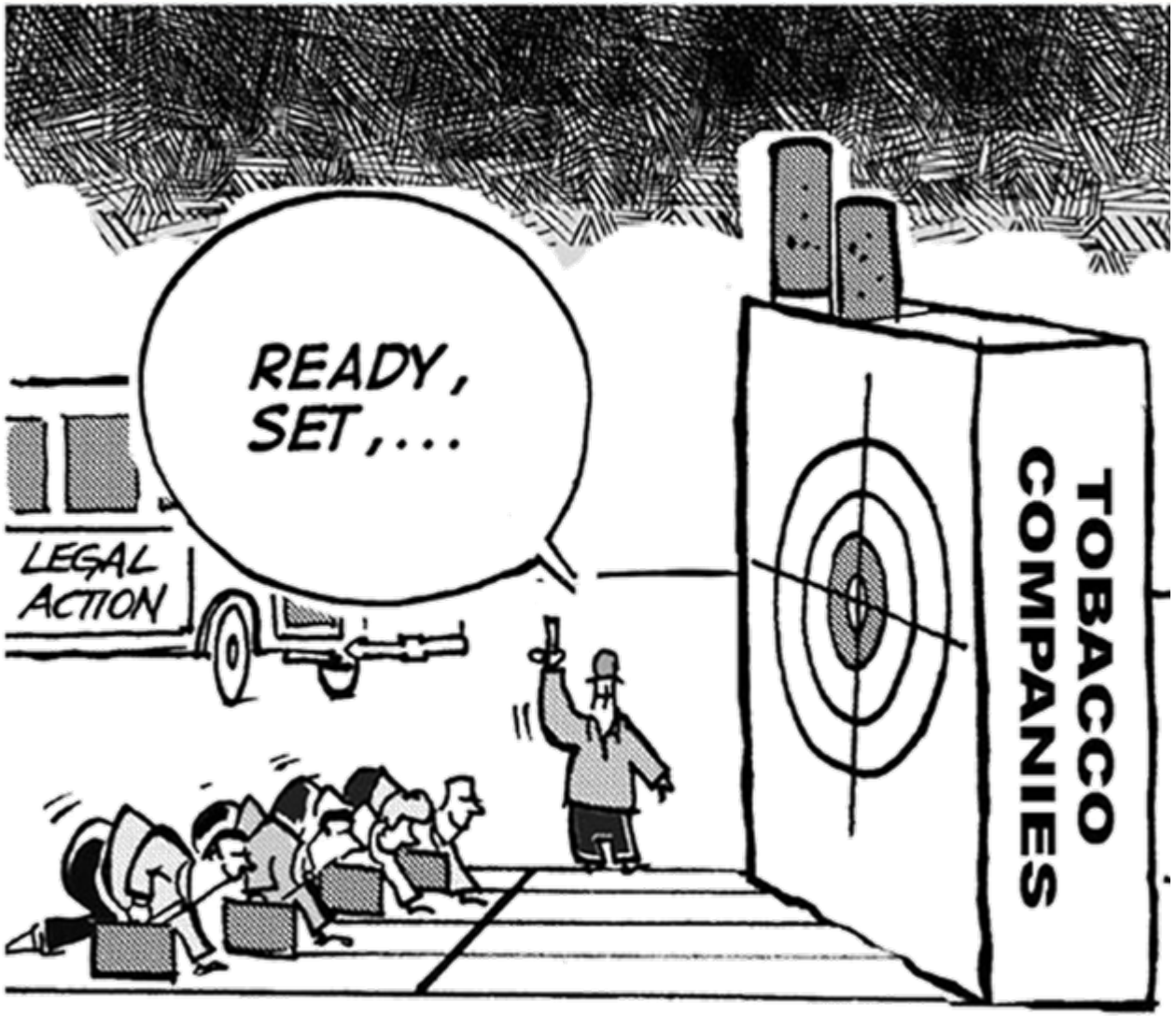
Enforcing Consumer Protection Laws: Model from the 1994-2004



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Consumer Protection Laws: Overview

- Based on Federal Trade Commission (FTC) laws
- State consumer protection laws have broad prohibitions:
  - "Capable of misleading"
  - "Violates public policy"
  - "Unfair"
  - "Concealing or omitting a material fact in selling product"
  - misrepresenting "characteristics or benefits..."
- Injunctive relief
- No proof of harm to collect penalties
- Potential exposure – billions

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Consumer Protection Laws: Big Tobacco Model

- States and feds used consumer protection laws to seek:
  - Reimbursement for health costs paid by Medicaid and other state payors for health effects of smoking
  - Fines for every cigarette sold based on:
    - concealed safety information
    - misleading advertising
  - Injunctive relief modifying
    - advertising practices
    - funding awareness of health risks
  - Private plaintiffs' lawyers were paid over $13 billion of over $350 billion dollar resolution

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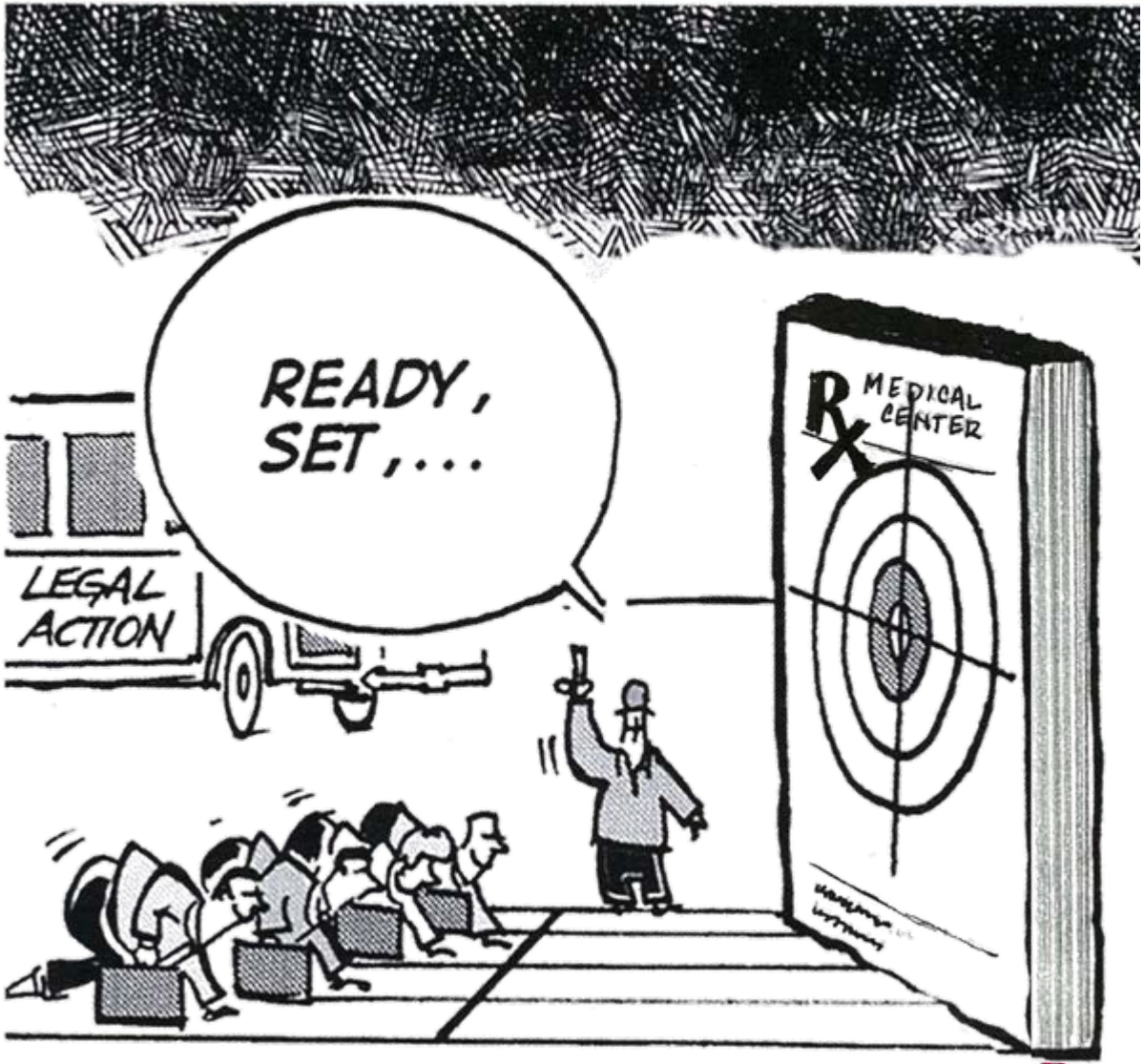
Targeting Pharma/Medical Devices: 2004-Current



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Targeted Activities of State Consumer Protection Investigations

- Clinical Trial Disclosures
- Adverse Event Disclosures
- GMP Violations
- CME
- Safety Advisory Boards
- Off Label Promotion
- Copy Approval or Medical/Legal/Regulatory Review

Targeted Activities of State Consumer Protection Investigations

- Grant Functions
- Physician Payment Disclosures
- Sampling
- Advertising and Promotional Standards in the FDCA ("substantial clinical evidence")
- Use of DTC
- Sales Force Compensation
- Any Violation of FDCA

Consumer Protection: Who is Lined up Against You?

- Individual state attorneys general lawsuits
  - Early pharma example: Spitzer v. GSK
  - Recent example: Oregon v. McNeil
- DDMAC and state attorney generals align
- Multistate investigations focused on
  - Civil investigations
  - Executive committee, but ultimately dealing with individual sovereigns
- Private plaintiff bar
  - Contingency fee payment
  - Aligned with whistleblowers and others

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DDMAC and State AG's Align: Yaz Example

The Yaz resolution "is a great example of collaboration between the FDA and State Attorneys General. By working together, we can achieve excellent results and double our efforts to clean up misleading advertising in the marketplace. This significantly benefits the public by ensuring that consumers are not misled about information relating to their health."

Tom Abrams
Director of the FDA's Division of
Drug Marketing, Advertising and Communications

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DDMAC and State AG's Align: Yaz Example

"Our understanding from our friends at FDA ... was that we provided additional leverage and that additional leverage was instrumental in terms of" producing an "effective corrective advertising program that was broader than would have been achieved by FDA alone … The days of pushing the envelope are perhaps in the past." That vision and enforcement power have led some to conclude that states may present a ***"super FDA"***.

David Hart
Oregon Assistant Attorney General

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Budget Crunches and Profit Motivations

- Plaintiffs' personal injury bar as special assistant to attorney general
- Fee arrangements
  - Contingency fees
  - Portions of penalties collected
- Challenges to fee arrangements
  - Janssen v. Pennsylvania
  - Merck v. Kentucky

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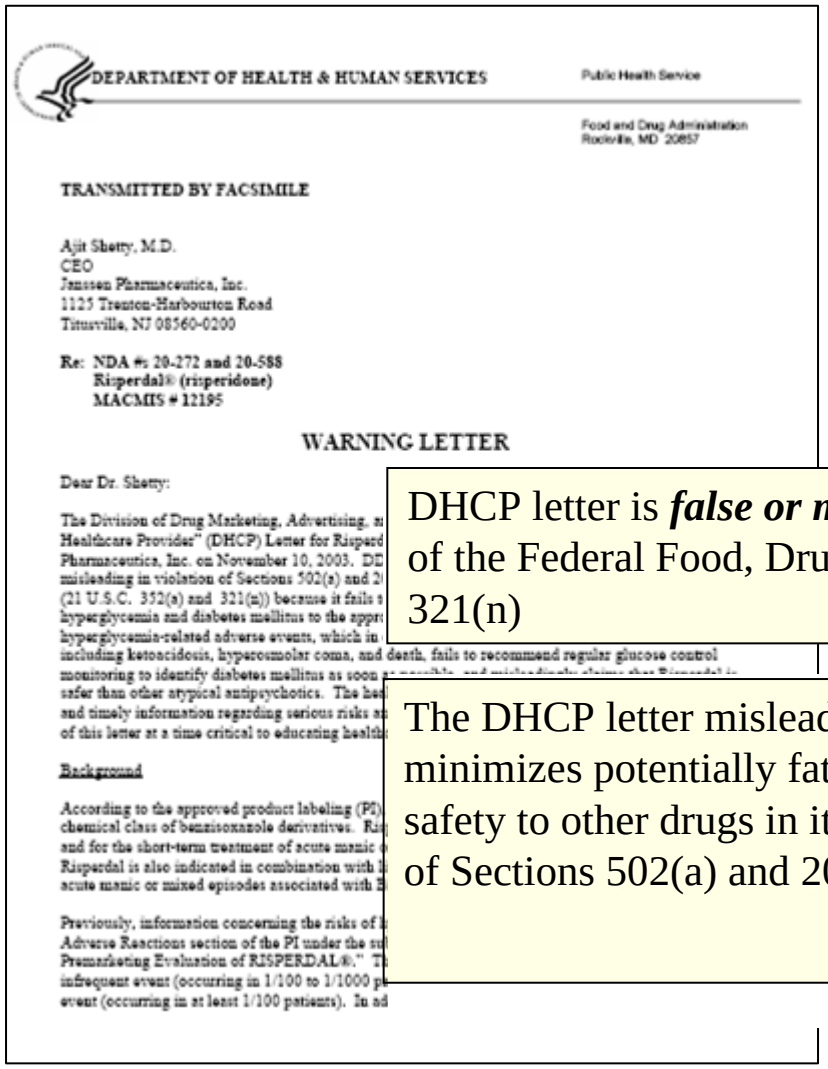
Case Studies – *Janssen* Trials: Louisiana and South Carolina

Key facts:

- Janssen sent Dear Healthcare Provider letter in 2004 placing in context diabetes class labeling as it related to Risperdal
- DDMAC disagreed with Janssen's interpretation of the data, and issued a Warning Letter

Case Studies – *Janssen* Trials: Louisiana and South Carolina



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Ajit Shetty, M.D.
CEO
Janssen Pharmaceutica, Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Re: NDA #s 20-272 and 20-588
Risperdal® (risperidone)
MACMIS # 12195

WARNING LETTER

Dear Dr. Shetty:

The Division of Drug Marketing, Advertising, a
Healthcare Provider" (DHCP) Letter for Risperd
Pharmaceutica, Inc. on November 10, 2003. DD
misleading in violation of Sections 502(a) and 2
(21 U.S.C. 352(a) and 321(n)) because it fails t
hyperglycemia and diabetes mellitus to the appr
hyperglycemia-related adverse events, which in
including ketoacidosis, hyperosmolar coma, and death, fails to recommend regular glucose control
monitoring to identify diabetes mellitus as soon
safer than other atypical antipsychotics. The let
and timely information regarding serious risks a
of this letter at a time critical to educating health

Background

According to the approved product labeling (PI),
chemical class of benzisoxazole derivatives. Ris
and for the short-term treatment of acute manic
Risperdal is also indicated in combination with l
acute manic or mixed episodes associated with B

Previously, information concerning the risks of i
Adverse Reactions section of the PI under the su
Premarketing Evaluation of RISPERDAL®." T
infrequent event (occurring in 1/100 to 1/1000 p
event (occurring in at least 1/100 patients). In ad

DHCP letter is ***false or misleading*** in violation of Sections 502(a) and 201(n) of the Federal Food, Drug and Cosmetic Act (Act) (21 U.S.C. 352(a) and 321(n)

The DHCP letter misleadingly omits material information about Risperdal, minimizes potentially fatal risks associated with the drug, and claims superior safety to other drugs in its class without adequate substantiation, in violation of Sections 502(a) and 201(n) of the Act (21 U.S.C. §§ 352(a) and 321(n)).

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Case Studies – *Janssen* Trials: Louisiana and South Carolina

Key facts:

- Janssen disagreed with DDMAC but issued a corrective letter three months later
- State AGs sued Janssen claming that the Warning Letter was proof of Janssen's "false and misleading" conduct, violating consumer protection laws
- Janssen disputed claims arguing statement was true when made and has further support today

Janssen Trials

- Judicial Conclusions:
  - Whether statements were true or not is irrelevant
  - Issue is whether there was scientific support at the time
  - Jury never heard that by 2007 Risperdal labeling differed from others in the class of antipsychotics
  - Jury found:
    - the Dear Healthcare Provider Letter was “false and misleading”
    - the labeling of the product did not adequately warn of the diabetes risk
    - the labeling and DHCP letter violated applicable consumer protection laws

Louisiana Verdict

OFFICE OF THE ATTORNEY GENERAL
State of Louisiana

JAMES D. "BUDDY" CALDWELL

RECENT NEWS
10/15/2010

State Wins $257.7 Million in Suit Challenging Risperdal Marketing Practices

Attorney General Buddy Caldwell obtained a jury verdict in the amount of $257,679,500 against Janssen Pharmaceutica, Inc. and its parent company Johnson & Johnson for violating the state's Medical Assistance Programs Integrity Law (MAPIL). The jury found that in 2003 & 2004 Jansen and J & J made misrepresentations minimizing its drug Risperdal's link to diabetes in order to obtain funds from the Medicaid program.

Under MAPIL the Attorney General is charged with the duty to protect the fiscal and programmatic integrity of the medical assistance programs from companies that engage in fraud, misrepresentation, abuse, or other ill practices to obtain payments to which they are not entitled.

Attorney General stated, "This verdict sends a loud message to those who knowingly try to defraud the system. Those who deceive the state must pay."

The state alleged that J & J and Janssen sent "Dear Doctor" letters to more than 7,500 Louisiana health care providers stating that Risperdal was safer than other competing brand name antipsychotic drugs, and made more than 27,000 similar marketing calls. The U.S. Food and Drug Administration previously warned J & J that it made false and misleading claims that minimized the risk of diabetes associated with Risperdal and overstated the drugs supremacy to rival medicines.

The Opelousas jury imposed a penalty of $7,250 for each of the 35,542 violations of the state's Medical Assistance Programs Integrity Law.

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Janssen Verdict: South Carolina

- Court imposed a penalty for every sample of Risperdal provided with inadequate labeling
- Court imposed penalty for every Dear Healthcare Provider letter sent to South Carolina physicians
- Maximum penalties of $5000.00 per violation would equal $2.675 billions dollars
- Court imposed penalties of $327 million
- Case on appeal

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Regulation through Attorney General Consent Decrees

- Companies that have resolved claims and are subject to Consent Decrees with States Attorneys General in the past few years include:
  - Astra Zeneca
  - Bayer
  - BMS
  - Cephalon
  - GSK
  - Guidant
  - Janssen
  - Lilly
  - McNeil
  - Pfizer
  - Purdue
  - Schering-Plough
- Consent decrees have become emerging compliance standards

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Case Study – Key Settlement Terms of State AG Consent Decrees

	Bayer	Purdue Pharma	Guidant	Merck	Cephalon	Lilly	Pfizer
Promotional activities: No claims that are false, misleading or deceptive	√	√		√	√	√	√
FDA-approved uses and patient profiles				√		√	√
Direct to consumer advertising: Reviewed by FDA				√			√
Dissemination of off-label information: Separate from promotional activity		√			√	√	√
Clinical trials and studies: Must not be misrepresented	√			√		√	√
Disclosure of payments to consultants and speakers						√	√
Sales bonuses: Not based solely on sales volume		√			√		
Grants and CME: Must be disclosed, and non-promotional		√		√		√	√
Publication authorship: Substantial contribution and final approval				√			√
Data Safety Monitoring Board: No conflicts of interest			√	√			
Sampling				√		√	√
Educational events: Cannot sponsor or fund events if speaker will recommend product or promote off-label uses		√			√		
Establish abuse and diversion detection program		√					
Employ a patient safety officer			√				
Annually report to the public worldwide failure data			√				
Comprehensive compliance program					√		

The Future:
States Attorney General Litigation

- State attorney general litigation
  - Allows attorney generals to enter health care debate
  - Perceptions of ineffective FDA enforcement
  - Provides revenue source in the face of budget pressures
  - Perceptions that any attack on pharma will lower price of medicines

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Implications

- The promotional approval process:
- Implications of DDMAC letter
  - May spark investigations
  - Evidence of “false and misleading” conduct
- Responses to DDMAC letters
  - Drafted understanding impact on potential future litigation or attorney general litigation

Implications

- Handling parallel proceedings
  - The attack against you is coordinated, cannot operate with tunnel vision
  - DOJ investigations, personal injury litigation, regulatory action all can be related
  - DDMAC working the AG's who are working with the plaintiffs' bar, who are working with relators

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