

# OFF-LABEL MARKETING OF PRESCRIPTION DRUGS AND DEVICES

Hamline University School of Law  
April 25, 2008

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# MEDICAL DEVICE AND DRUG MANUFACTURERS:

- Cozy financial relationships between and among owners;
- Aggressive off-label marketing practices;
- Direct consumer advertising issues;
- Unapproved or adulterated devices;
- Safety issues;
- Industry paid for or sponsored research;
- Clinical trial issues;
- FDA indications;
- Aggressive or inappropriate marketing efforts;
- Shortcuts in quality;
- ***KICKBACKS. . . . .KICKBACKS. . . . .KICKBACKS***

# FEDERAL ENFORCEMENT EFFORTS

- **Most civil and criminal cases have been and will continue to be driven by *qui tam* plaintiffs and their counsel;**
- **Much better coordination between Feds and State AG's;**
- **High level of coordination between civil and criminal prosecutors;**
- **Over 160 federal *qui tam* actions spread across many judicial districts against device and pharmaceutical manufacturers.**

- **Zimmer (\$169.5m);**
- **Stryker non-pros with court approved monitor;**
- **Biomet (\$26.9m);**
- **Smith & Nephew (\$28.9m);**
- **De Puy (\$84.7m);**
- **Blackstone Medical**
- **Medtronic – July 2006**
- **NuMed (\$4.5m)**

# **RECENT MEDICAL DEVICE SETTLEMENTS AND INVESTIGATIONS, CONT'D**

- **Many of these settlements involved a close look at financial relationships (kickbacks) with orthopedic surgeons for hip and knee replacements**
- **Senior counsel to the Office of the Inspector General warned in 2006 that medical device manufacturers would be the next logical target for false claims prosecution**
- **Wall Street Journal Online reported that Orthofix has set aside \$50m for settlement of physician kickback claims (1/4/08)**
- **May, 2007 - US House Oversight and Government Reform Committee issued document subpoenas to Johnson & Johnson and Boston Scientific as part of an investigation into the off-label marketing of new drug-eluting stents**

# RECENT PHARMACEUTICAL SETTLEMENTS AND INVESTIGATIONS

- **Serono (\$704m, criminal and civil);**
- **Bristol-Myers Squibb (\$515 m);**
- **Cephalon, Inc. (\$425m);**
- **Schering Plough (\$255m, \$435m incl. criminal);**
- **Purdue Frederick Co. (\$160m, \$634.5m incl. criminal and private civil actions) – misbranding OxyContin;**
- **InterMune, Inc. (\$36.9m);**
- **Eli Lilly (\$36m);**

# **RECENT PHARMACEUTICAL SETTLEMENTS AND INVESTIGATIONS, CONT'D**

- **Pfizer (\$34.7m);**
- **Jazz Pharmaceuticals (\$20m);**
- **Purdue Pharma (\$19.5m);**
- **Pharmacia (\$15m);**
- **Cell Therapeutics (\$10.5m);**
- **Medicis Pharmeceuticals Corporation (\$9.8m);**
- **Otsuka (\$4m)**

# **RECENT PHARMACEUTICAL SETTLEMENTS AND INVESTIGATIONS, CONT'D**

- **A January 30, 2008 New York Times Article reports Eli Lilly was negotiating \$1 billion settlement with state and federal governments for off-label marketing of Zyprexa.**
- **Merck – After a 2007 \$4.85 billion settlement of 27,000 lawsuits alleging Vioxx injuries, Merck is the subject of a federal grand jury probe and investigations by 31 state attorneys general regarding off-label marketing of Vioxx.**

# **RECENT PROPOSED LEGISLATION WOULD PERMIT LIMITED OFF-LABEL MARKETING**

- **February, 2008 – FDA proposed guidelines would allow manufacturers to give doctors reprints of medical journal articles about uses of drugs and medical devices that haven't won agency approval**
- **Rep. Henry Waxman (D-Cal.): “It's a conflict of interest for the company to be promoting sales when they haven't been able to establish that a drug is safe and effective through the rigorous FDA process.”**
- **FDA: such articles "can contribute to the practice of medicine and may even constitute a medically recognized standard of care."**