

# Enforcement in the Pharmaceutical Industry

Michael K. Loucks  
First Assistant U.S. Attorney  
United States Attorney's Office  
District of Massachusetts  
October 2008

Views expressed are speaker's personal opinions

# Drug Industry Cases

<b>Years</b>	<b>Total Recoveries</b>	<b>Pharma Cases</b>	<b>%</b>
<b>1991-1995</b>	<b>856,600,000</b>	<b>171,000,000</b>	<b>19.9</b>
<b>1996-2000</b>	<b>3,602,040,776</b>	<b>274,440,776</b>	<b>7.6</b>
<b>2001-June 2008</b>	<b>11,407,609,404</b>	<b>5,742,282,179</b>	<b>50.3</b>
<b>Totals</b>	<b>15,866,250,180</b>	<b>6,187,722,255</b>	<b>39.0</b>

# Off Label Promotion

- TAP Prosecution, 2001:
  - *Not* an off-label case
  - Two components: kickbacks, best price
- Parke Davis Prosecution, 2004:
  - First major drug industry off-label case
  - *Not* the first off-label prosecution of an FDA regulated product
- Majority of pending investigations involve *off-label* promotion allegations
- *No end in sight*

# Labeling

- Claims made to sell product –whether in promotional pieces, statements made by sales reps, advertisements, must be consistent with approved labeling. 21 C.F.R. 202.1(e)(4).
- Off-label claims include both unapproved indications *and* claims about product that exceed statements on the label

# Intended Use: 21 CFR 201.128

- The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

# Intended Use

- But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced ... by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.
- Section 352 provides that a drug is misbranded if it does not contain adequate directions for use

# "Promotion"

- Law does not define nor prohibit certain types of promotional activities
- Law prohibits distribution with intent to distribute the product for uses that are not approved: to distribute a misbranded product or an adulterated product
- Examples
  - product with no approvals
  - Product with one approval

# Free Speech v. Off-Label Promotion

- No free speech right to promote a device for an off-label use
  - There is a tension between the “exchange of reliable scientific data and information within the health care community and the statutory requirements that prohibit companies from promoting products for unapproved uses.”
    - Virginia Bd. Of Pharmacy v. Virginia Citizens Consumer Council, inc., 425 U.S. 748, 765 (1976).

# Off-Label Promotion

- Government has a substantial interest in the regulation of medical devices and in “subjecting off-label uses to the FDA’s evaluation process.”
- “[P]ermitting defendants to engage in *all* forms of truthful, non-misleading promotion of off-label uses would severely frustrate the FDA’s ability to evaluate the effectiveness of off-label uses.”
  - United States v. Caputo, 288 F. Supp. 2d 912 (N.D.Ill. 2003).

# Schering Example

- Intron A approved, treatment of numerous conditions, *but not* superficial bladder cancer
  - The label contained no directions for use for that indication
  - Sales reps engaged in wide spread marketing for that indication
- Hypothetical question often posed: Why can't those reps engage in truthful dissemination about information regarding that drug's use in treating that cancer?

# Not the issue

- Speech, by itself, is not the issue
- Crime: distribution of product intending that it be used for an indication, where the label does not provide adequate directions for use in treating that condition
- The speech becomes a part of our proof of the criminal conduct

# Example

- "Bank X has a bank branch on Main Street and every Tuesday morning at 8:00 a.m., the armored car company makes a delivery of six bags."
  - Truthful statement
  - Factually accurate
- Protected speech or evidence of a crime?

# Impact on sales and marketing

- Sales activity dependant on “marketplaces”:
  - The person/entity using, prescribing, or controlling use:
    - a doctor, a nursing home administrator
  - The person/entity paying for the product or in whose budget the item falls:
    - the retail patient; HMO management, the pharmacy department of a hospital, the benefits administrator
  - The person or entity controlling access:
    - E.g., P & T committee for a hospital; the P & T committee of a bellwether hospital; medical director of a dialysis facility

# Relevance

- The marketplace at issue affects the sales activity and the legal relevance of that activity:
  - Sales activity is willful: deliberately engaged in with a targeted purpose
  - Must be funded: budget must be prepared, presented, reviewed, approved
  - Is monitored for success: has the targeted purpose been satisfied
  - Is modified to meet changes in the marketplace