PRESCRIPTION DRUG LITIGATION

WISCONSIN DEPARTMENT OF JUSTICE

PUBLIC PROTECTION UNIT

- Environmental Enforcement
- Consumer Protection
- Antitrust Litigation

ANTITRUST LAW

- Regulation of business conduct and organization.
- Purpose is to promote competition to protect the free market and benefit consumers.

ANTITRUST LAW – FEDERAL & STATE

- Sherman Act
- Clayton Act
- Federal Trade Commission Act
- Wisconsin's "Little Sherman Act" and "Little Clayton Act."
  - *Wis. Stats. Ch. 133.*

SUBOXONE

- Antitrust Lawsuit filed in 2016.
- Plaintiffs are 42 States and Commonwealths, led by the State of Wisconsin.
- Defendants are involved with the development, manufacture, and sale of Suboxone (buprenorphine/naloxone).

SUBOXONE

- Suboxone is a opioid replacement therapy for the treatment of opioid dependency.
- Until generic buprenorphine/naloxone was introduced to the market in 2013, Suboxone was the only replacement maintenance therapy that could be prescribed in an office setting and taken by patients at home.

SUBOXONE

- 2002 Suboxone introduced as a sublingual tablet and granted "orphan drug" status by the FDA.
- The orphan drug designation provided the defendants with a seven year exclusivity period, expiring on October 8, 2009.
- Exclusivity = freedom to market as a brand-name drug, free from generic competition.
- After the exclusivity period expires, generic drugs may enter the market.

HATCH-WAXMAN ACT

- Federal law passed with the intended purpose of pushing down prescription drug pricing by encouraging the manufacture of generic drugs by the pharmaceutical industry.
- Allows generic drugs to come onto the market more quickly through an Abbreviated New Drug Application. The ANDA process allows generic drug manufacturers to get drugs approved ***without*** replicating the costly and time-consuming clinical trials required of the original drug manufacturer.
- To be approved, an ANDA must demonstrate that the generic drug: (a) has the same active ingredients; (b) is pharmaceutically equivalent (same dosage form and strength); and (c) is bioequivalent (exhibiting the same drug absorption characteristics).

GENERICS

- Oral drugs that are proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA.
- Oral drugs that carry the FDA's AB generic rating in a particular category may be substituted by pharmacists for a physician's prescription for a brand-name drug ***without*** the physician's approval.
- When generic drugs enter the market (typically at lower prices), it is not uncommon for the brand-name manufacturer to lose 80 percent or more of its brand-name sales.
- The entry of generics creates competition and genuine competition results in lower prices.

PRODUCT HOPPING - SUBOXONE TABLETS TO SUBOXONE FILM

- Defendants create Suboxone Film.
- Change to the dosage form (tablets to film) means generic tablets would not be pharmaceutically equivalent. ***No AB rating***. Pharmacist may ***not*** substitute generic tablets if Film is prescribed.
- Film was patented and defendants enjoy a period of exclusivity (NO COMPETITION).

MARKET CONVERSION – TABLETS TO FILM

- Campaign to drive the Film to market before the generic tablets could enter.
  - Promoting superiority of the Film over the Tablets to doctors, payors, and pharmacists.
  - Pricing the Tablets so that they were more expensive than the Film.
  - Hiring and compensating its sales force to incentivize them to sell the Film.
- September 2012, defendants publicly announce that they intended to discontinue Suboxone Tablets due to defendants' concerns regarding the safety of the Tablets. Defendants withdrew the Suboxone Tablets in March 2013.

DELAY OF GENERICS INTO THE MARKET

- Manufacturers of generic drugs filed ANDAs in 2009.
- Generic ANDAs were ultimately approved in February 2013.
- By the time generic tablets were introduced Suboxone Film constituted more than 85% of the market.

DELAY OF GENERICS INTO THE MARKET

- Defendants failed to cooperate in good faith with the generic manufacturers in the submission of a joint Risk Evaluation and Mitigation Strategies (REMS) for the Tablets.
- Defendants filed a Citizen Petition asking the FDA to withhold approval.
- Due in part to the acts of the Defendants, the applications for generics were not approved until February 2013.

SUBOXONE LAWSUIT

- Defendants engaged in an overarching conspiracy to prevent and delay generics to maintain their monopoly profits.
- The lawsuit seeks:
  - Injunctive Relief
  - Disgorgement
  - Penalties

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- 2013-14 sudden price spikes in a number of generic drugs.
- Congressional hearings.
- United States Department of Justice Criminal Investigation.
- State AGs' investigation and lawsuits.

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- 2016 State AGs' lawsuit:
  - 46 States.
  - 18 Corporate Defendants, and two corporate executives, all who were involved in the manufacture and sale of 15 generic drugs.
- 2018 State AGs' lawsuit:
  - 50 States and Territories.
  - 20 Corporate Defendants, and 15 corporate executives, all who were involved in the manufacture and sale of more than 100 generic drugs.

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- Both lawsuits allege the defendants engaged in conspiracies to:
  - Fix prices
  - Rig bids
  - Allocate drug markets
  - Other anticompetitive conduct
- Defendants claim the increased prices are the result of market forces and drug shortages.

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- Relief sought:
  - Injunctive remedies
  - Disgorgement
  - Civil Penalties

CONSEQUENCES OF ANTICOMPETITIVE CONDUCT IN PHARMACEUTICAL SALES

- Anticompetitive conduct results in higher prices.
- Affects hospitals and pharmacists.
- Affects health insurance premiums and plans.
- Affects Medicare and Medicaid programs.
- Affects individual consumers.

WISCONSIN DEPARTMENT OF JUSTICE

R. Duane Harlow

Assistant Attorney General

Wisconsin Department of Justice

(608)266-2950

harlowrd@doj.state.wi.us