



ARNOLD & PORTER LLP

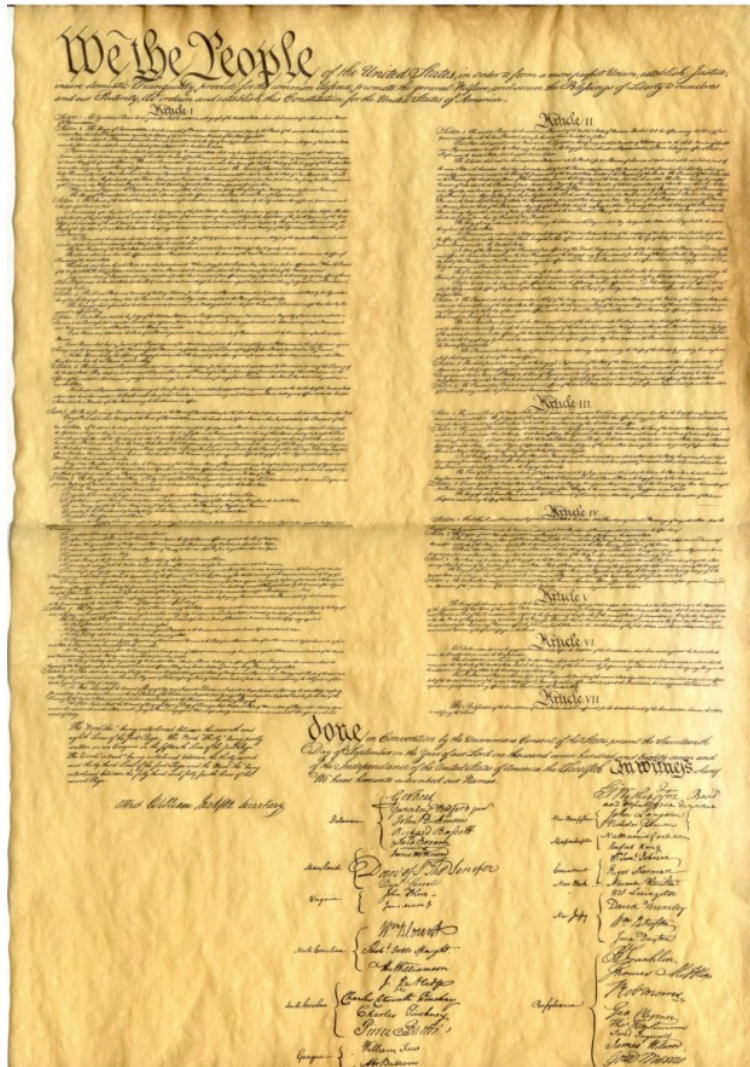
# PREEMPTION AND THE PHYSICIAN PAYMENTS SUNSHINE ACT

Robert N. Weiner  
October 22, 2008

# TOPICS

- Overview of Preemption
- Recent Developments
- Consequences and Strategies

# OVERVIEW OF PREEMPTION



## SUPREMACY CLAUSE

Federal law is the  
“supreme Law of the  
Land”

Judges in every state are  
bound “any Thing in the  
Constitution or Laws of  
any state to the Contrary  
notwithstanding.”

# OVERVIEW OF PREEMPTION

## Cross Currents

- Pro-Business v. States Rights
- Pro-Regulatory v. Pro-Plaintiff
- Intertwined Issues

# OVERVIEW OF PREEMPTION

Express Preemption

Implied Preemption

Field Preemption

Conflict Preemption

Impossibility

Obstacle

# OVERVIEW OF PREEMPTION

## Key Issues

- Presumption Against Preemption
- Congressional Intent

# OVERVIEW OF PREEMPTION

## Presumption Against Preemption



# OVERVIEW OF PREEMPTION

## Congressional Intent





# TOPICS

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# RECENT DEVELOPMENTS

## Preemption Preambles

- NHTSA
- CPSC
- FRSA
- FDA

# RECENT DEVELOPMENTS

## *Riegel v. Medtronic Inc. (2008)*



# RECENT DEVELOPMENTS

## Express Preemption Under the MDA

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter

# RECENT DEVELOPMENTS

## *Altria Group, Inc. v. Good*

- **Express Preemption of Consumer Fraud Claims Involving Tobacco Products**
- **Argued October 6, 2008**

# RECENT DEVELOPMENTS

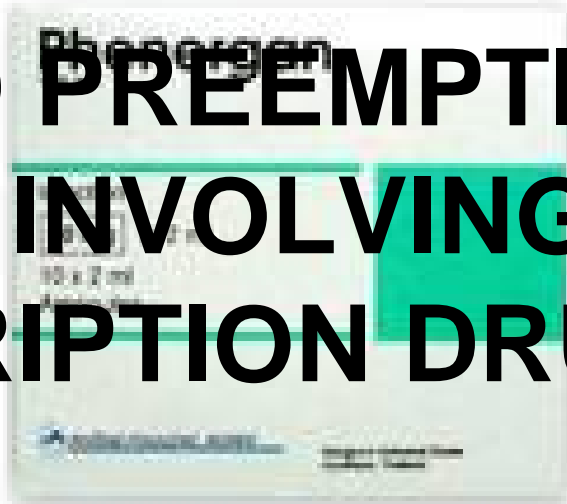
## *Altria Group, Inc. v. Good*

No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter

# RECENT DEVELOPMENTS

## *Wyeth v. Levine*

**IMPLIED PREEMPTION OF  
CLAIMS INVOLVING  
PRESCRIPTION DRUGS**



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# CONSEQUENCES AND STRATEGIES



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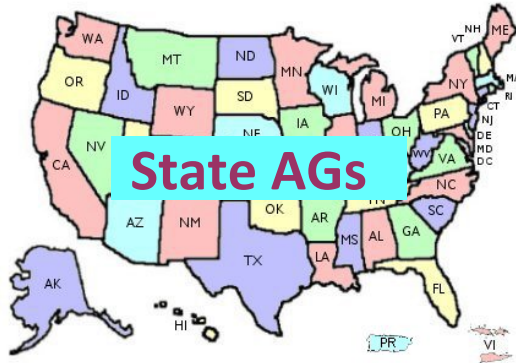
## Medical Device Safety Act of 2008

S. 3398

H.R. 6381

No Effect on Liability Under State Law-  
Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.

# CONSEQUENCES AND STRATEGIES



## Preemption Opponents



# CONSEQUENCES AND STRATEGIES

## Physician Payments Sunshine Act

Sec. 1128G(d):

RELATION TO STATE LAWS.—The provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State relating to the disclosure or reporting of information regarding payments or other transfers of value provided to covered recipients by applicable manufacturers to the State or to any other governmental entity for purposes of including such information in any State-sponsored database or other repository of information.

# CONSEQUENCES AND STRATEGIES

## State Laws Potentially Preempted

### Laws and Regulations on:

- Clinical Trial Registration?
- Prescriber Identifiable Data?
- Marketing Disclosure?
- Gifts and CME?
- Licensing of Sales Representatives?

# CONSEQUENCES AND STRATEGIES

## State Laws Potentially Preempted

