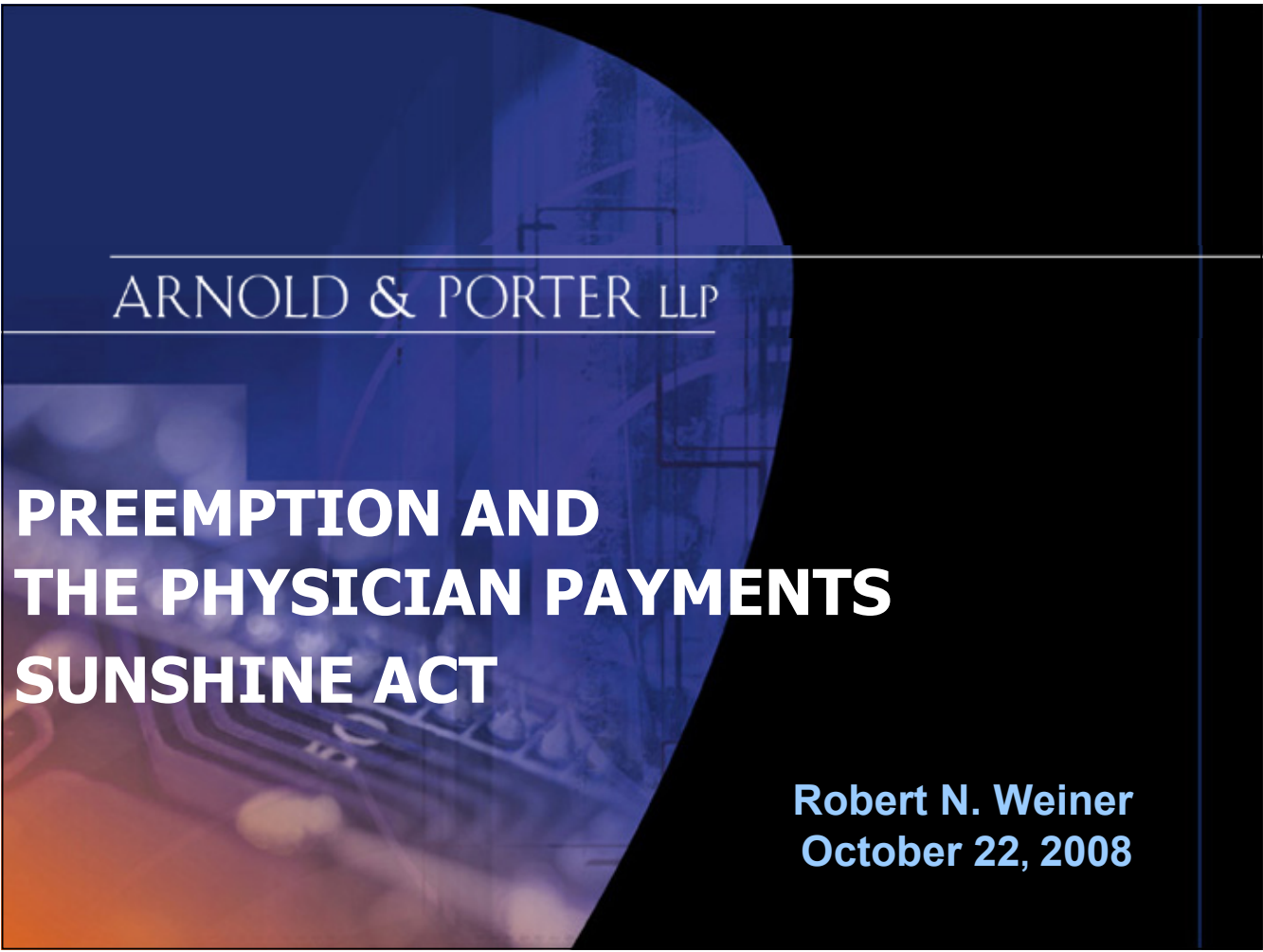




ARNOLD & PORTER LLP

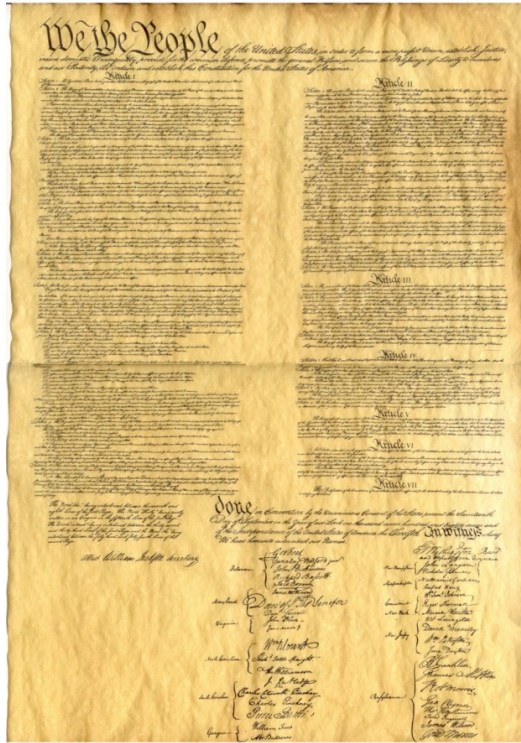
PREEMPTION AND THE PHYSICIAN PAYMENTS SUNSHINE ACT

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.”

arnoldporter.com

OVERVIEW OF PREEMPTION

Cross Currents

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

arnoldporter.com

OVERVIEW OF PREEMPTION

Express Preemption

Implied Preemption

Field Preemption

Conflict Preemption

Impossibility

Obstacle

arnoldporter.com

OVERVIEW OF PREEMPTION

Key Issues

- Presumption Against Preemption
- Congressional Intent

arnoldporter.com

OVERVIEW OF PREEMPTION

Presumption Against Preemption



arnoldporter.com

OVERVIEW OF PREEMPTION

Congressional Intent



arnoldporter.com

TOPICS

- Overview of Preemption
- Recent Developments
- Consequences and Strategies

RECENT DEVELOPMENTS

Preemption Preambles

- NHTSA
- CPSC
- FRSA
- FDA

RECENT DEVELOPMENTS

Riegel v. Medtronic Inc. (2008)



arnoldporter.com

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

arnoldporter.com

RECENT DEVELOPMENTS

Altria Group, Inc. v. Good

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

arnoldporter.com

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

arnoldporter.com

RECENT DEVELOPMENTS

Wyeth v. Levine

IMPLIED PREEMPTION OF CLAIMS INVOLVING PRESCRIPTION DRUGS

arnoldporter.com

TOPICS

- Overview of Preemption
- Recent Developments
- Consequences and Strategies

arnoldporter.com

CONSEQUENCES AND STRATEGIES



CONSEQUENCES AND STRATEGIES

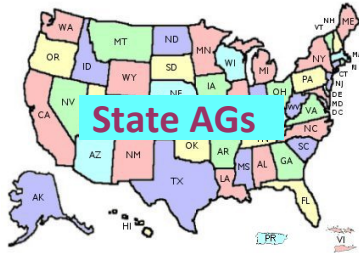
Medical Device Safety Act of 2008

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



The NEW ENGLAND
JOURNAL of MEDICINE
(Editors)



Congressman
Henry Waxman

Preemption Foes



ConsumersUnion.org
Nonprofit Publisher of Consumer Reports



David
Kessler



Formerly the Association of Trial Lawyers of America

arnoldporter.com

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.

arnoldporter.com

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?

arnoldporter.com

CONSEQUENCES AND STRATEGIES

State Laws Potentially Preempted



arnoldporter.com