

The Public's Health and the Law in the 21st Century
5th Annual Partnership Conference

Concurrent Session

Vaccine Law 101

Tuesday, June 13, 2006
10:30-12:00 pm

Moderator: Georges C. Benjamin, MD, FACP, Executive Director, American Public Health Association, Washington, DC

Panel: Eric Hargan, JD, Principal Associate Deputy Secretary, U.S. Department of Health and Human Services, Washington, DC

Daniel O'Brien, JD, General Counsel, Public Health Services, Office of the Maryland Attorney General, Baltimore, MD

Susan Sherman, JD, Senior Attorney, Office of General Counsel, U.S. Department of Health and Human Services, Washington, DC

Session Purpose:

Vaccines are indispensable tools to protect the health of Americans against conventional infectious diseases as well as threats posed by emerging infectious diseases and by potential bioterrorist attacks.

This session will be a primer in the federal and state legal framework for vaccine licensing, distribution, allocation, and related functions central to the success of vaccination programs. The panelists will describe and comment on vaccine laws in three broad contexts important to public health practitioners, health care providers, policy makers, and legal counsel:

- Federal laws that govern vaccine manufacture, licensing, issuance of vaccination guidelines, federal purchase of vaccine supplies, injury compensation and liability considerations—in non-emergency settings;
- The general types of state laws that provide for the purchase and allocation of vaccine supplies, vaccination of groups at high risk of infectious disease, and authorization for specified health care providers to administer vaccinations—also in non-emergency settings; and
- Major federal and state laws that govern vaccine supplies during public health emergencies—e.g., legal authorities underlying the Strategic National Stockpile, allocation of scarce vaccine supplies, and actions against hoarding and price gouging.

Learning Objectives:

By the close of this session, conference participants will be able to:

- Describe the principal components of the federal and state legal framework for vaccine production and use;
- Outline the roles of federal and state agencies in vaccine production and use and describe related jurisdictional issues; and
- Describe major, vaccine-related legal issues that tend to arise during responses to public health emergencies, and approaches to resolving those issues.

Session Convener:

Public Health Law Program, CDC

Resource Materials:

Pertinent federal authorities include:

Titles II, III, XXI, and XXVII of the Public Health Service Act

Title V of the Federal Food, Drug, and Cosmetic Act

The Stafford Act (Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 USC 68)