

**Vaccine Law – 101  
HHS Public Health Authorities**



**Susan E. Sherman, JD, MHS  
Office of the General Counsel**

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**HHS Public Health Authorities**

- Public Health Service Act
- Food, Drug, and Cosmetic Act
- Social Security Act
- Stafford Act
- Other Federal-wide authorities (e.g., procurement, personnel)

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**Recent Legislation**

- Public Health Security and Bioterrorism Preparedness and Response Act
- Homeland Security Act
- Smallpox Emergency Personnel Protection Act
- Project BioShield Act
- Public Readiness and Emergency Preparedness Act

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## Research and Development

- Domestic and International
- Surveillance, Epidemiology, Laboratory Research, Clinical Research
- National Vaccine Program
- Project BioShield
- Priority Countermeasures

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## Food and Drug Administration Product Approval

- Approved Products /Approved Uses
- Accelerated Approval
- Investigational New Drugs
- Emergency Use

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## Production

- National Vaccine Program
- Certification of Clinical Laboratories
- Licensing of Biological Products
- Production for Government Use

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### Procurement

- Strategic National Stockpile
- Federal Acquisitions
- Project BioShield
- Priority Contracts

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### Distribution

- National Vaccine Program
- Strategic National Stockpile
- Public Health Service, U.S. Commissioned Corps
- Other Federal Agencies
- States and Locals
- Private Sector

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### Administration

- Mandatory/ Voluntary
- Informed Consent
- Health Care Provider Qualifications

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## Quarantine

- Interstate
- International
- States and Locals
- Enforcement

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## Safety

- National Vaccine Program
- Vaccine Information Sheets
- Vaccine Adverse Event Reporting System

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## Payment

- Medicare
- Medicaid
- Vaccines for Children
- Grants to States

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## Liability Protection

- Federal Tort Claims
- Federal Employee Compensation
- Contractor Indemnification
- National Vaccine Injury Compensation
- Smallpox Liability Protection and Compensation
- Public Readiness and Emergency Response Declarations

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## Questions

HHS Office of the General Counsel  
(202) 690-7741

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