Immunization Laws: Impact of Non-Medical Exemptions

Tuesday, November 4, 2014
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Immunization Laws: Impact of Non-Medical Exemptions

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Moderator Introduction

Dan Orenstein
Deputy Director, Network for Public Health Law — Western Region

- J.D. and Certificate in Law, Science and Technology from Arizona State University Sandra Day O’Connor College of Law,

- Research interests/areas of expertise:
  - Public Health Law and Ethics
  - Infectious Disease Policy
  - Emergency Legal Preparedness
  - Health Care Reform
Panel Introduction

Allison N. Winnike
Research Assistant Professor, University of Houston Law Center
Health Law & Policy Institute

- J.D. from Georgetown University Law Center

- Research interests/areas of expertise:
  - Public Health Emergency Preparedness and Response
  - Immunization Law and Policy
  - Health Legislative Drafting
  - Health System Transformation
  - Health Information Technology
Panel Introduction

Dorit Rubinstein Reiss
Professor of Law, UC Hastings College of Law

- LLB Faculty of Law, Hebrew University, Jerusalem; Ph.D. in Jurisprudence and Social Policy, University of California Berkeley

- Research interests/areas of expertise:
  - Administrative Law
  - Comparative Law
  - Torts: Immunization Law and Policy
Panel Introduction

Anna C. Dragsbaek
President and CEO, The Immunization Partnership

- J.D. from University of Houston

- Research interests/areas of expertise:
  - Promoting and fostering childhood immunizations
  - Advocacy and education to individuals, community partners and healthcare providers
  - Immunization Project at Texas Children’s Hospital
History of Compulsory Immunization Laws and the Development of the Anti-Vaccine Movement

Allison N. Winnike, J.D.
Benefits of Immunizations

• Greatly reduces disease, disability and death
• Touted as one of the 10 great public health achievements in the 20th century
• Global eradication of smallpox (1980)
• Near-elimination of polio globally
• Elimination of measles in U.S. (2000)
• Near-elimination of diphtheria in U.S. (one case since 2004)

Image of Smallpox patient from George Henry Fox, Photographic Illustrations of Skin Diseases 21 (2nd ed. 1886).
Overview of Compulsory Immunization Laws

• All states have compulsory immunization laws for children as a condition of school attendance
• Some states have compulsory immunization laws for attendance at schools of higher education
• Some states have compulsory immunization laws for health care workers
• Many states provide for compulsory immunization during a declared public health emergency
Federal Role

• Commerce Clause (Article I, Section 8, Clause 3)
  – Immigrant vaccination requirements
  – Military vaccination requirements

• Federal appropriations
  – Vaccines For Children (VFC) program
  – Section 317 Immunization Program
  – Vaccine research and development

• Advisory Committee on Immunization Practices (ACIP)

• National Vaccine Injury Compensation Program (VICP)
Legal Authority for Compulsory Immunization Laws

• State police power to protect the health, safety, morals, and general welfare of the people
• State tools to protect public health include compulsory immunization requirements
• Police powers must balance duty to protect community health with personal liberty
• Action must be necessary to protect public health and not arbitrary or unreasonable
History of Compulsory Immunization Laws

• 1809- Massachusetts law granting local boards of health authority to require vaccination “when necessary for public health or safety”

• 1827- City of Boston ordinance requiring vaccination for school attendance

• 1855- Massachusetts law requiring vaccination for school attendance
  – Trend spread from northeast states to midwest, southern, and western states over next few decades
Supreme Court Cases

• *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
  – Upheld use of police powers to protect the public’s health
  – Imposed limits on individual liberty if necessary to protect public health

• *Zucht v. King*, 260 US 174 (1922)
  – Upheld a city ordinance requiring smallpox vaccination for school attendance
  – Deference to states in imposing health regulations
Early Anti-Variolation Sentiment

- Variolation during Boston Smallpox Epidemic of 1721 promoted by the influential minister Cotton Mather
- 2% fatality rate among variolated volunteers
- 14% fatality rate among the rest of Boston
- Angry resident threw grenade into Mather’s house for promoting variolation

When the *Granado* was taken up, there was found a Paper so tied with String about the Fuse, that it might out-Live the breaking of the Shell, which had these words in it; *Cotton Mather, You Dog, Dam you: I’ll inoculate you with this, with a Pox to you.*¹

Variolation to Vaccination

• Edward Jenner developed first vaccine in 1796

• Vaccination differs from variolation by using similar agent (cowpox) to build immunity

Early Anti-Vaccination Sentiment

Caricature showing cows emerging from parts of people's bodies by James Gillray (1802).
Modern Anti-Vaccine Movement

- DTP (diphtheria-tetanus-pertussis) vaccine
  - Publicity that pertussis vaccine caused epilepsy, otherwise injured or killed children from 1979 study by British Dr. David Miller
  - Increase in vaccine-injury lawsuits led to creation of Vaccine Injury Compensation Program in 1988
  - Study could not be replicated after several attempts and determined in 1988 that data was incorrectly labeled and incomplete
Modern Anti-Vaccine Movement

- MMR (measles-mumps-rubella) vaccine
  - Publicity of 1998 study by British Dr. Andrew Wakefield in *The Lancet* of 12 children; Wakefield claimed vaccine caused autism
  - Despite multiple attempts, study could not be replicated
  - Deemed fraudulent, paper fully retracted in 2010 at which time Wakefield was stripped of medical license for serious professional misconduct
Modern Anti-Vaccine Movement

• Thimerosal vaccine preservative
  – Mercury-based preservative used in vaccines since 1930s to prevent contamination
  – Phased-out of vaccine use from 1999 to 2001 due to general concerns over environmental mercury poisoning
  – As a result of calls for removal, some in autism community thought it caused autism
  – 2004 Institute of Medicine report rejects causal relationship between thimerosal and autism
Consequences Anti-Vaccine Movement

• A vocal anti-vaccine community continues to wield political power
  – Increase in personal belief/philosophical exemption laws
  – Lower rates and delayed vaccinations, which is especially dangerous in clustered areas which now lack herd immunity
  – Increase outbreaks of pertussis and measles
Types of Exemptions

• Medical
  – All 50 states allow

• Religious
  – 48 states allow (except Mississippi and West Virginia)

• Personal Belief/Philosophical
  – 19 states allow
Indicates states with Personal Belief exemptions, in addition to Medical and Religious exemptions
Kindergarten Exemptions for 2013-2014 School Year

“Estimated percentage of children enrolled in kindergarten who have been exempted from receiving one or more vaccines* and with <90% coverage with 2 doses of measles, mumps, and rubella (MMR) vaccine — United States, 2013–14 school year” from CDC, Vaccination Coverage Among Children in Kindergarten — United States, 2013–14 School Year, MMWR 63(41);913-920: 917.
Immunization Requirements: Current Law

Dorit R. Reiss
Children deserve a good education and good health. Immunization requirements help protect both.
Variations in Ease of Getting Exemption:

- Form only exemption.
- Notarized.
- Medical: any review of doctor’s signature? Which medical reasons?
- Letter from church member.
  - But: see below.
- Sincerity review of religious exemption – intensive?
- Empirical evidence: ease of exemption affects rates of exemptions.
Legislative Trends (Lilvis, Kirkland):

- Examining anti-vaccine legislative achievements.
- Recently:
  - Unable, or almost, to get anti-vaccine laws passed.
  - Successes in blocking pro-immunization laws.
Informed Refusal Statutes:

- Washington, 2011
- California, 2012
- Oregon, 2013
## Differences:

<table>
<thead>
<tr>
<th></th>
<th>Who can sign?</th>
<th>Online Module?</th>
<th>Religious exemption?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Washington</strong></td>
<td>MD, DO, ND, PA, ARNP</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>California</strong></td>
<td>MD, DO, NP, ND (some), PA,</td>
<td>No</td>
<td>Yes, kind of</td>
</tr>
<tr>
<td></td>
<td>credentialed school nurses</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oregon</strong></td>
<td>MD, DO, ND, NP, or PA.</td>
<td>Yes</td>
<td>No</td>
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Colorado and HB1288

Initially:
- Educational requirement: healthcare provider signature or online module.
- School required to publish rates of immunization.

As Passed:
- State to create educational materials.
- No change to PBE.
- Schools to provide immunization rates if requested.
Religious Freedoms:


BUT:


- Challenging West Virginia’s lack of religious exemption.
- Court applied strict scrutiny & rejected claim.
- “[T]he state’s wish to prevent the spread of communicable diseases clearly constitutes a compelling interest.”
Limits on Religious Exemptions:

• Cannot be limited to organized religion:

• Some states still use that language.
Limits on Religious Exemptions:

- Unless statute required, cannot evaluate sincerity:
- Vulnerable to abuse, and indeed abused.
Are religious exemptions constitutional?


Healthcare workers and mandates

NURSES AGAINST MANDATORY VACCINES

SHOULD REALLY BE CALLED

NURSES THAT SHOULD FIND ANOTHER CAREER

Nurses Who Vaccinate Are Nurses Who Care

www.nurseswhовaccinate.org
Influenza Mandates:

- 20 States have statutes (Stewart and Cox).
  - Only a handful have enforcement mechanisms.
- Growing number of hospitals adopt.
  - Enforcement varies.
- Variation on specifics.
- Substantial political controversy.
Legal Issues:

Constitutional issues: religion again.

Employment issues:
- Most states: at will employment.
- Americans with Disabilities Act.
- Civil Rights Act of 1964.
- Collective Bargaining Struggles.
Valent v. Board of Review

- Nurse refused to vaccinate:
  - Willing to wear a mask.
  - No religious reason.

- Dismissed. Denied unemployment benefits.

- Court reinstated benefits:
  - Violation of nurse’s free speech.
  - Can’t limit exemptions to those whose beliefs are religious.
Valent v. Board of Review: Evaluation

- First Amendment grounds: probably wrong.
- Exemption might be unconstitutional:
  - Favors organized religion.
- Not required to provide religious exemption.
- Pitfalls in providing the right one.
States laws:
Thank you!

Questions? Comments?

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Institute for Immunization Law and Policy
Impact of Pro-Immunization Policy

Texas Adolescent Immunizations

- Tdap: 2008 = 40.8%, 2011 = 80.7%, 2013 = 86.1%
- Meningitis: 2008 = 37.4%, 2011 = 79.1%, 2013 = 87.6%
- 2nd Varicella: 2008 = 31.5%, 2011 = 73.1%, 2013 = 93.6%
Nothing Much Happened Today

Lorem Ipsum In libris graecis appetere mea. At vim odio lorem omnes, pri id iuvaret partiendo. Vivendo menandri et sed. Lorem volumus blandit cu has. Sit cu alia porro fuisset.

Ea pro natum invidunt repudiandae, his et facilisis vituperatoribus. Mei eu ubique altera senserit, consul eripuit accusata has ne.

In libris graecis appetere mea. At vim odio lorem omnes, pri id iuvaret partiendo. Vivendo menandri et sed.
Impact of Anti-Immunization Legislation

K-12th Grade Students With Personal Belief Exemptions
Texas, 2003-2013

Number of Personal Belief Exemptions

School Year

2003 to 2004
2004 to 2005
2005 to 2006
2006 to 2007
2007 to 2008
2008 to 2009
2009 to 2010
2010 to 2011
2011 to 2012
2012 to 2013

www.immunizeUSA.org
Measles Outbreak 2014: 592 Cases Reported In US After Disease 'Eliminated' In 2000

By Howard Koplowitz  
@howardkoplowitz  
h.koplowitz@ibtimes.com  
on September 08 2014 9:09 AM
Charter Workgroup

- Baylor College of Medicine
- California Immunization Coalition
- Endeavor Management
- Grassroots Advocates
- Immunization Action Coalition
- Immunize Nevada
- Sabin Vaccine Institute
- Centers for Disease Control and Prevention

- The Immunization Partnership
- The Network for Public Health Law
- Rekha Lakshmanan
- Hastings School of Law
- University of Houston Law Center
- University of Texas School of Public Health
- West Virginia Immunization Network
Houston, August 2014
Purpose of the Institute

• Provide a forum for experts across disciplines to advance immunization law and policy

• The recognized central and united source that policy makers, advocates, influencers, and the media rely upon for immunization policy discourse

• Translate complex immunization research into model policies and laws to help support stakeholders in their advocacy efforts
The Sweet Spot

Health Policy
- e.g., Law Schools, General Health Think Tanks, CDC, State Legislatures

Public Health
- e.g., State Health Depts, CDC, State Coalitions, Schools of Public Health

Economics
- e.g., Think tanks, Economists, Academic Institutions, Vaccine Industry

INSTITUTE FOR IMMUNIZATION LAW AND POLICY
What are the unmet needs?

Single Voice
- Immunization advocates need a credible, collaborative and unified voice, where possible, supporting effective immunization laws and policies.

Legislative Expertise
- Advocates, legislators, and staff need tools that help translate research and science into easy-to-execute laws and policies.

Focused Repository
- Immunization stakeholders need a single repository of credible immunization policy and legal information, ideas and research.

Organized Network
- Immunization stakeholder across disciplines need an organized network to share ideas and connect with others.
Logic Model

**INPUT**
- Formal network
  - Staff
  - Subject matter experts
  - Disparate data
  - Technology
  - Stakeholder engagement

**WORK**
- Single voice
  - Convene meetings/conference
  - Create website
  - Cultivate relationships
  - Develop collateral/products
  - Work with media

**PRODUCTS**
- Robust information repository
  - Model statutes
  - White papers
  - Talking Points
  - Fact Sheets
  - Network of SMEs

**OUTCOMES**
- Legislative and advocacy expertise
  - Empowered Advocates and improved immunization laws and policies

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[THE IMMUNIZATION PARTNERSHIP](www.immunizeUSA.org)
Market Strategy

Assemble a core group of experts
- Mix of disciplines and fields (e.g., academic, private, public, advocacy etc.)
- Organize leading conference of experts

Create useful resources for end users
- Open, timely, and frequent communication
- Simple to use and understand
- Functional and robust repository that is heavily used by stakeholders

Differentiate from other stakeholders
- Focus on immunization laws and policies
- Be the resource to advocates and influencers--not the public

Develop media relationships through:
- Press releases, interviews, position papers, white papers, social media
- Oral consultation (briefing seminars for policy makers and the media)
Core Markets & Products

- Model Laws
- Legislative Briefs
- Policy/Legal Research
- Economic Impact Assessments

- Amicus Briefs
- Media Presence
- Policy/Legal Research
- Identify Future Hot-Button Issues

- Forums
- Conferences
- Tools for Sharing & Collaborating
- Online Repository (Website)

- Tool Kits
- Best Practices
- Fact Sheets
- Access to “Experts” Registry

- Expert Stakeholders
- National Immunization Laws & Policies

- Local Advocacy Groups
- State Immunization Laws and Policies
# Implementation Strategy

## PRE-PLANNING

- Stakeholder charter meeting
- Obtain seed funding
- Canvas funding pipeline
- Recruit Executive Director
- Write strategic plan
- Conduct stakeholder survey
- Create charter documents
- Identify research opportunities

## PHASE I

- Volunteers commit to deliverables
- Begin knowledge accumulation for repository
- Recruit advisory panel
- Grassroots launch
- Identify working committees
- Identify research grant opportunities

## PHASE II

- Identify support staff
- Conduct stakeholder conference
- Develop website
- Develop stakeholder relationships (on-going)
- Build sample resources
- Set up registry of resources
- Cultivate media relationships

## PHASE III

- Execute on identified priorities from stakeholder conference
- Go LIVE!
- Begin issuing digital media posts and white papers

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[THE IMMUNIZATION PARTNERSHIP](www.immunizeUSA.org)
How Is Success Measured?

• **Removing Silos**
  – Number of collaborative research opportunities and publications (online, reports etc.)

• **Impacting Policies**
  – Number of states using model statutes (where applicable) to develop vaccine supporting legislation
  – Number of states limiting or stalling vaccine hindering legislation using Institute’s tool kits and resources

• **Impacting Practice**
  – Number of downloads of best practice collateral
  – Active use of resources in practice and integrated into local advocacy SOP

• **Reaching the Audience**
  – Number of media hits
  – Frequency of media consults
Expert Advisory Council

EXPERT ADVISORY COUNCIL

Public Health  Academic Expertise  Advocacy Groups  Private Sector  Health Law  Health Economics
Questions?

Contact Anna C. Dragsbaek
acdragsbaek@immunizeusa.org

Institute for Immunization Law and Policy
Q&A

Please type your questions in the Q&A panel.
Upcoming Webinars

Thank you for attending.

Please join us for these upcoming webinars:

Alcohol Law and Policy: Lessons Learned from the Field
Thursday, November 20, 2014 — 1 PM Eastern

Global Health Law with Lawrence O. Gostin, University Professor and Founding O’Neill Chair in Global Health Law, Georgetown University
Thursday, December 11, 2014 — 3 PM Eastern

For more information email jrose@networkforphl.org