

Measles Outbreak: Public Health Authority, New York City's Immunization Mandate, and the Current Legislative Landscape

June 4, 2019

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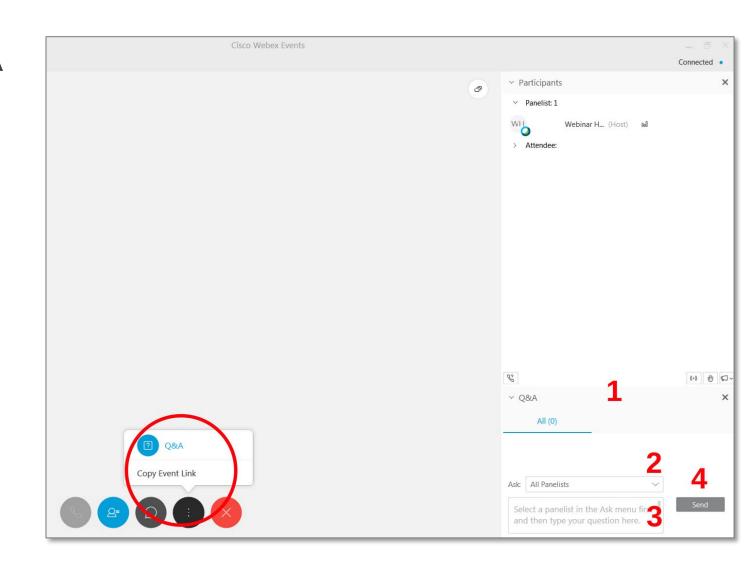






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Moderator



Donna Levin, National Director, the Network for Public Health Law

- J.D., Northeastern University School of Law
- Research interests/areas of expertise:
 - Crisis Standards of Care
 - Newborn Screening
 - Genetics and Privacy Laws
 - Emergency Public Health Response
 - Health Care Cost Reform



Presenter



Wendy E. Parmet, Matthews University Distinguished Professor of Law and Faculty Director, Center for Health Policy and Law, Northeastern University

- J.D., Harvard University
- Research interests/areas of expertise:
 - Bioethics
 - Civil Rights
 - Disability Law
 - Medical Issues
 - Public Health Law



Presenter



Thomas Merrill, General Counsel, New York City Department of Health and Mental Hygiene

- J.D., University of Connecticut School of Law
- Research interests/areas of expertise:
 - Outbreak Investigations
 - Mental Health
 - Obesity Prevention
 - Tobacco Control



Presenter



Allison Winnike, President/CEO, The Immunization Partnership

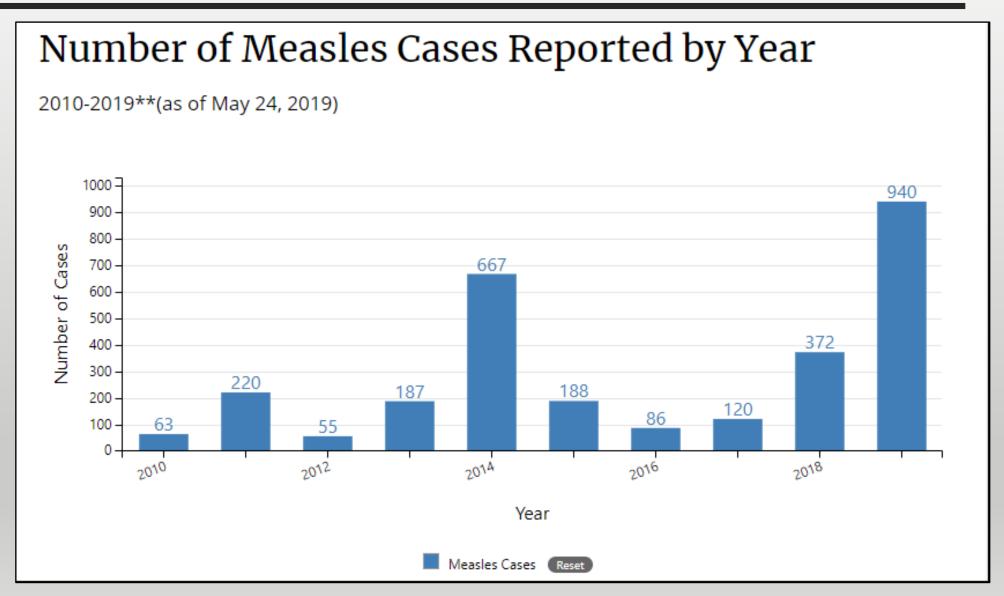
- J.D., Georgetown University Law Center
- Research interests/areas of expertise:
 - Vaccine Advocacy Legislation
 - Immunization Law and Policy
 - Emergency Response
 - Infectious Diseases

VACCINE LAW: JACOBSON & BEYOND

Wendy E. Parmet
Center for Health Policy and Law
Northeastern University



The Return of Measles



CDC data as of May 24, 2019.

What Can Law Do to Increase Rates of Vaccination?

- The History of Vaccine Law
- Jacobson v. Massachusetts, Legacy & Questions
- Contemporary Case Law, Litigation over SB 277
- Revisiting Religious Exemptions
- Federal Intervention
- Moving Forward

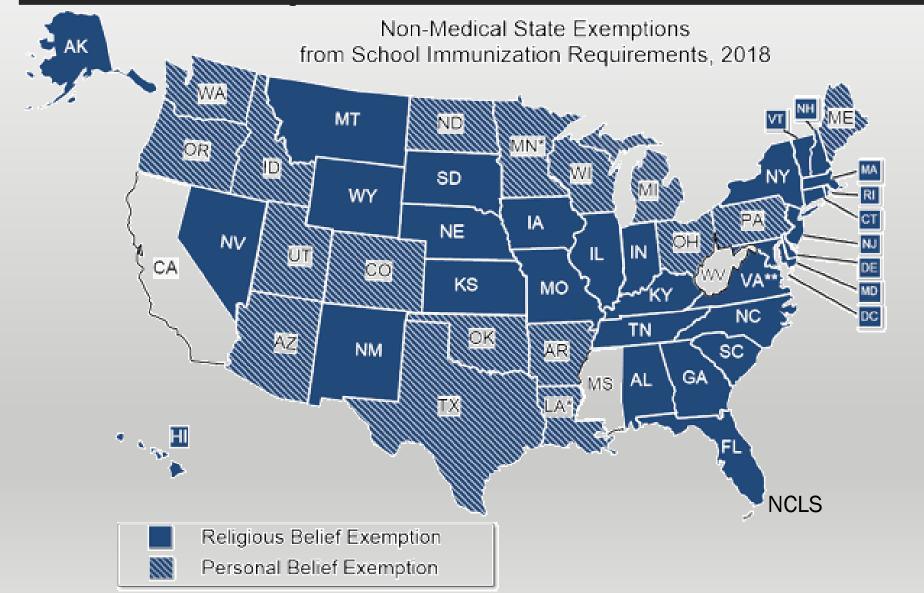
Vaccine Law in History

Pre-17 th century	Variolation practiced in the Middle East and Asia
1721	Cotton Mather introduces variolation to N. America amidst controversy
1796	Edward Jenner develops the smallpox vaccine
1813	Congress passes "An Act to Encourage Vaccination"
1823	Boston mandates vaccination for school attendance
1855	Massachusetts enacts first state vaccine mandate
1905	Supreme Court decides <i>Jacobson v. Massachusetts</i>
1922	Supreme Court upholds school-based vaccine law in Zucht v. King

Vaccine Law in History, cont.

1955	Polio Vaccine/Cutter Incident
1964	ACIP formed
1968	Half of all states require vaccination for school attendance
1981	All states have vaccine mandates
1986	Congress passes National Childhood Vaccine Injury Act
1998	The Lancet publishes Wakefield's paper linking vaccines to autism
2015	Disneyland outbreak leads to SB 277
2019	Number of measles cases rise, Washington abolishes PBE, Maine becomes 4 th state to abolish PBE and religious exemptions.

46 States Provide for Religious and/or Personal Belief Exemptions



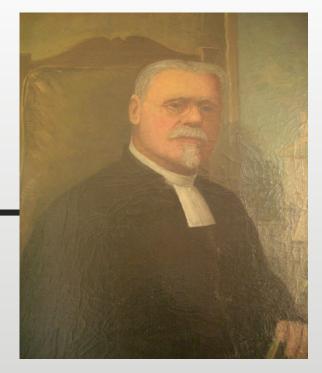
Updates:

- Washington

 abolished
 personal belief
 exemption
- Maine abolished personal belief and religious exemptions

Jacobson v. Massachusetts 197 U.S. 11 (1905)

- Rejected 14th Amendment challenge to Massachusetts law requiring smallpox vaccination during an outbreak.
- Emphasizes that the police power allows state to pass reasonable health regulations.
- "Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others."
- Held that the legislature may delegate the power to require vaccination to the Board of Health.

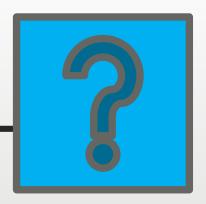


Jacobson: The Rorschach Test



- "We say necessities of the case, because it might be that an acknowledged power of a local community to protect itself against an epidemic threatening of the safety of all, might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere..."
- "[T]he police power ... may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts."

Left Unclear



- Free Exercise Claims: Couldn't be brought in 1905.
- Must there be an **outbreak**? How severe?
- Can the state **forcibly** vaccinate an individual?
- Can the **state quarantine** individuals who refuse to be vaccinated?
- How do contemporary due process cases, especially those affirming the right to make one's own medical decisions, affect vaccine law?

Post-Jacobson Supreme Court Cases

Zucht v. King, 260 U.S. 174 (1922)

Affirms Texas law requiring children to be vaccinated to attend school
 even in absence of an outbreak.

Prince v. Massachusetts, 321 U.S. 158 (1944)

 Stating in dicta: "Thus, he cannot claim freedom from compulsory vaccination for the child more than for himself of religious grounds."

Employment Div. Dep't Human Resources v. Smith, 494 U.S. 872 (1990)

 Neutral law of general applicability does not violate the Free Exercise Clause.

Jacobson's Continuing Clout

- Despite significant changes in due process law, courts continue to rely on *Jacobson* to uphold school vaccination laws, and rule that states need not provide religious exemptions.
 - Phillips v. City of New York, 775 F.3d 538 (2d Cir. 2015)
 - Workman v. Mingo County Bd. of Educ., 419 F. App'x 348 (4th Cir. 2011)



The California Litigation

- SB 277, which abolishes religious and PBEs, has been challenged as violating:
 - Substantive due process/state right to privacy
 - The Free Exercise Clause
 - Equal protection
 - State constitutional right to education
 - Violation of IDEA
 - RICO



- To date state and federal courts have rejected all challenges:
 - Love v. State Dep't of Educ., 29 Cal. App. 5th 980 (2018)
 - Brown v. Smith, 24 Cal. App. 5th 1135 (2018)
 - Whitlow v. California, 203 F. Supp. 3d 1079 (S.D. Cal. 2016)
 - Middleton v. Pan, 2018 WL 58234 (C.D. Cal. 2018), appeal dismissed, 2018 WL 7501283 (9th Cir. 2018).

The Paradox of Religious Exemptions

Although the Free Exercise Clause does not require religious exemptions, states that have such exemptions can face Establishment Clause and Equal Protection challenges:

- When an exemption favors some religions over others. *Dalli v. Bd. of Education*, 358 Mass. 753 (1971).
- If the exemption favors religious objectors over secular objectors. *Brown v. Stone*, 378 So. 2d 218 (Miss. 1979).
- If the state officials have excessive authority to determine religious doctrine or sincerity.

LePage v. State, 18 P.3d 1177 (Wyo. 2001).

On the Horizon: Reconsidering Religious Objections

Smith and hybrid claims

Hobby Lobby and the "undue burden" test — But note the exception for vaccines

Federal Conscience Regulations, 45 CFR Pt. 88 - Do not override state vaccine laws.

Beyond School Mandates

Compulsory Vaccination Philadelphia, 1991

Quarantines and Travel Bans



Federal Intervention

"If states continue to grant "wide exemptions" they're "going to force the hand of federal health agencies."

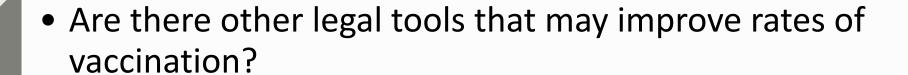
Former FDA Commissioner Scott Gottlieb

Federal agency action would raise questions of:

- Federalism
 - Commerce & Commandeering
 - Power to Tax & Spend
- Statutory Authority
- Religious Freedom Restoration Act



Moving Beyond Jacobson



Do vaccine laws (unintentionally) increase resistance?

 What changes can we make to vaccination laws and policy to enhance trust and compliance?

 How do we respond if measles or vaccine-preventable diseases become endemic?

The 2019 Measles Outbreak

Thomas Merrill

General Counsel

New York City Department of Health and Mental Hygiene

Measles 101

- Characterized by fever and rash
- Highly contagious
 - Airborne and droplet transmission
 - Remains active for up to two hours
 - Infectious four days prior to rash
 - 90 percent of non-immune contacts will be infected
- Incubation period is 7-21 days
- Can be serious and even fatal
 - Complications include pneumonia and encephalitis
 - 1 to 2 child deaths per 1,000 children infected



Measles Resurgence

- > Had Been declared eliminated in the U.S. in 2000
- Since then, there have been periodic outbreaks as a result of importation of the virus by people infected while traveling outside of the U.S.
- ➤ 2013 NYC outbreak
 - > 58 cases
 - ➤ Was largest NYC outbreak since 1989-1991 measles insurgence and since measles was eliminated in the U.S.
 - > Caused by one unvaccinated adolescent who acquired measles in the United Kingdom
 - > Concentrated in Borough Park and Williamsburg among the Orthodox Jewish community
- Currently, there are large outbreaks throughout the world, including in Israel, Europe (Ukraine), Asia (Philippines, India), South America (Brazil, Venezuela), and Africa (Madagascar)
- Resurgence attributed to weak health systems, low vaccination rates, increased vaccine hesitancy, and anti-vaccination movement

Rockland County

- 28 percent of children unvaccinated
- Measles arrived with one traveler in September 2018; 225 cases as of May 8
- Emergency declared by County Executive on March 26 barring unvaccinated people from places of public assembly
- TRO issued on April 5 blocking its enforcement
 - Court refused to find that 166 cases was an "epidemic"
 - Order exceeded five day term specified in NY Executive Law



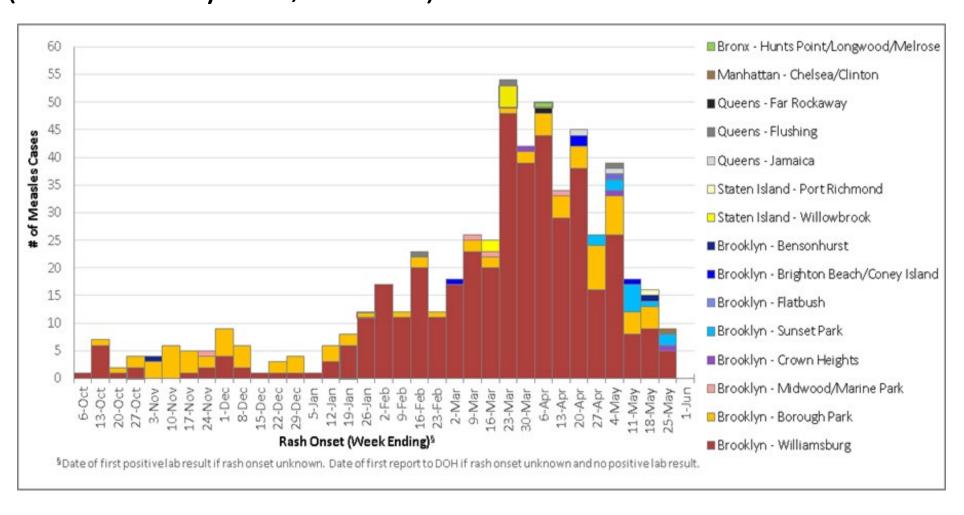
Epidemiology of the Current Outbreak (as of May 29, 2019)

- Time period: September 30, 2018 through May 29, 2019
- ≥550 confirmed cases
- ➤ 52 identified chains of transmission, 32 of which are active; 11 importations (Israel, UK, Ukraine, NJ, NYS)
- ➤ Age range: <1 year to 66 years of age
 - ➤ 56 (17%) children <1 year of age
 - ➤ 162 (49%) children 1-4 years of age
 - ➤ 66 (20%) children 5-17 years of age
- ≥25 hospitalizations; 6 persons admitted to Intensive Care Unit
- ➤ Almost all cases reside in Williamsburg (267 cases, 81%) or Borough Park (52 cases, 16%) Brooklyn and are members of the Orthodox Jewish community

Measles Cases by Neighborhood in NYC (as of 4/30/19)

Williamsburg	379
Borough Park	69
Midwood/Marine Park	4
Sunset Park	4
Brighton Beach/Coney Island	3
Crown Heights	2
Flushing	2
Bensonhurst	1
Far Rockaway	1
Hunts Point/Longwood/Melrose	1

Measles Outbreak, NYC 2018-2019: Epi Curve by Rash Onset and Neighborhood (as of May 28, 2019)



Anti-vaccination Propaganda



ome people choose to pproach a rabbinic authority for assistance in making vaccine decisions. We recommend consult ng a rabbi who is willing to look at the facts before drawing con-

Up until now, a lot of medical eliefs about vaccines have been

Halachic Points Of Interest

Does the "majority rule" apply since most doctors believe that the benefits of vaccines outweigh the risks?

accepted medical pro asserts that vaccines Does the identical *c thousands of doctors as more than one vo policy-making medic

Medical policymake acceptable for the insacrificed for the ber Government author that many children y or injured by vaccine to the loss of life as " However, in order to cine compliance and the goal of "disease o information about th of vaccines is intenti held from parents an

utism is a mental disorder characterized by impaired social capability, with trouble relating to other people, dif-

ing, restricted and repetitive behavior, and difficulty connecting to their surround ings. There are many

elements of autism

that make it an unusual condition Not only do most autistic children have the normal appear

ance of healthy children, they also usually lack a clear genetic abnormality that can account for their learning and social deficits. Another strange factor is that autism often appears as a sudden regression after a history of normal development. (15)

Common Adverse Reactions

The incidence of the following reactions vary; however even some of the more serious events listed below occur surprisingly frequently.

Serious reactions include: high fever. headache, swelling and pain, diarrhea, vomiting, high-pitched scream-

after just one shot, sometimes it is only after repeated insult that the child becomes disabled. Medical professionals usually deny

that a reaction contraindicates future boosters. In most cases they do not even believe that the reaction was caused by the vaccine altogether. They often convince parents,

against their own better indement that it is safe to continue regret for having been convinced to ignore reactions and continue with vaccines that subsequently led to their child's permanent disability or even

Caution Discarded

Some of us may remember a time when doctors were cautious enough to withhold a booster because of a severe reaction to a previous vac-

Do You Know What's In A Vaccine's

ev. cow heart. , chicken egg, oodandmore. ver, nerve, and

se blood, rab-

cted gastrom

organ potson.

he recipient's

RAL DNA

tially.(15,16) Researchers reported that autism was an extremely rare condition before 1943, when it was announced a a new mental disorder. (6) In the 1950s, less than 1 in 10,000 cases were reported.0

The U.S. has one of the highest rates of

autism in the world.(1) While the num-

bers continue to climb, according to the

CDC, as of March 2013, it is estimated that

1 in 50 American children suffer from the

disorder.(13) During the last half a century

the number of cases has grown exponen-

Many attempt to find a logical explanation for the growing incidence of this disorder. They claim that the increase in autism is merely an improvement in diagnostics; that there must have always been as many cases, they just went

undetected

► FORMALDEHYDE (FORMALIN) Mater constituent of embalantag fluid; potsonous if ingested. Probable carcinogen: suspected in gastrointestinal, liver, immune system, nerve, reproductive system, and respiratory. Poison. Linked to leukennia, brain, colon, and lymphatic cancer.

→ MICRO-ORGANISMS (often undetected) Live and killed viruses and bacteria or their textns. Millions of doses of polio vaccine were contaminated with monkey virus (SV-40), now turning up in human bone, lung lining (mesothelioma), brain tumors, and

B (ANTIBIOTIC)

Allergic reactions can range from mild to

Potsonous if ingested. Causes birth defects in experimental animals.

MERCURY (THIMEROSAL)

The second-most-toxic element on Earth (after Plutonium). Has an affinity to the brain, gut, liver, bone marrow, and kidneys. Minute amounts can cause brain/nerve damage. Symptoms of mercury toxicity are

TRI(N) BUTYLPHOSPHATE

Suspected kidney and nerve potson.

► NEOMYCIN SULFATE (ANTIBIOTIC)

How To Prevent Your Children From Being Damaged By Vaccines

year, more your If the increase in prevalence was truly a case of missed diagnoses, then new cases

cines are safe and risk free Vaccine Courts

How have povernmental apencies responded to the tremendous incidence of vaccine reactions? In 1986, there were only three pharmaceutical companies making vaccines. It was an

ing reaction to a vaccine, they are usually

told that this was not a vaccine reaction

are expected to voluntarily report severe

reactions. However, they often do not,

claiming that the event was not caused by

Despite this mounting evidence, the medical

at all, but an unrelated illness, Doctors

unpopular market, as they were all drowning in law-"I worked with Congress in suits for vaccine injury. In order to deal with the great number of adverse events. congress passed the National Childhood Vaccine Injury Act, ostensibly to help cover damages for vaccine-injured children Since that time vaccine

(founder of the Nottona)

cine injury] law and have watched it be turned into a cruel toke...the Department of Justice officials fight every claim, viewing every reward to a vaccine-injured child as and do cause harm."(13)

risks: that aside from a slight fe

ver or other mild reactions, dan-

Adverse Reactions

The CDC and FDA devel-

oped the Vaccine Adverse

Event Reporting System

available in the 1990s, Ev-

ery year over 12,000 adverse reactions are

voluntarily reported to the federal govern-

ment. This includes ER visits, permanent

injuries, and deaths. The FDA estimates

(VAERS) which became

to Vaccines

the rare instances that claimants succeed in win-

the early 1980s on that [vac

ning their suits. Congress established a "disability and death" tax on childhood vaccines. A percentage of the money from every shot goes into a special fund to compensate parents of children who have been seriously damaged or killed by vaccine

injuries must be taken

dollars are set aside for

to special vaccine courts

where billions of U.S. tax

https://issuu.com/peachmoms/docs/the vaccine safety handbook a4



Health Department Response

- ➤ Over 200 Health Department staff working on the outbreak
- ➤ Case and contact investigation
 - ➤ Set up dedicated call center
 - Station Health Department staff at one high volume facility at the epicenter of the outbreak to assist with potential exposures
 - ➤ Investigate all reported cases
 - ➤ Contact identification and notification (over 12,200 exposures)
- ➤ Public Health Laboratory has performed over 1,600 diagnostic tests
- ➤ Issued revised MMR recommendations for all children in affected communities

Excluding Unvaccinated Children

- While New York recognizes religious exemptions to school vaccination requirements, a local health department may order schools to exclude children with religious and/or medical exemptions during an outbreak
- Beginning in December, DOHMH began advising yeshivas and day cares to exclude unvaccinated children
- In April, 102 schools and daycares in Williamsburg were served with Orders directing them to exclude children
- NOVs issued for not complying or not cooperating with audits
- Five schools closed and required to submit CAPs
- Orders and audits led to better compliance

Public Health Emergency Declared

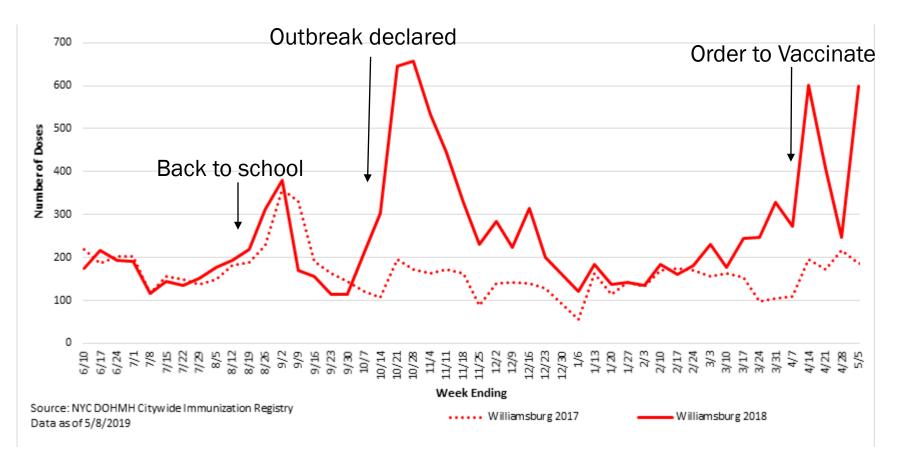


- Health Code §3.01 allows Commissioner to act
- Announced publicly in Williamsburg on April 9th
- Directed residents of ZIP codes 11205, 11206, 11221 and 11249 to be vaccinated within 48 hours
- Remained in effect until BOH meeting on April 17th
- https://www1.nyc.gov/assets/doh/ downloads/pdf/press/2019/emerg ency-orders-measles

Board of Health Resolution (4/17/19)

- Declared the outbreak in ZIP codes 11205, 11206, 11211 and 11249 to be a public health nuisance
- Continued the requirement that residents/students/workers in these affected ZIP codes be vaccinated (or have proof of immunity or be able to demonstrate medical exemption)
- Per Administrative Code §17-148, Order was served by publication in <u>City</u> <u>Record</u> and in local media
- Violations of the Order punishable by a \$1000 fine.
- Violations are daily and continuing
- https://www1.nyc.gov/assets/doh/downloads/pdf/notice/2019/board-of-health-resolution-measles.pdf

MMR Vaccine Uptake Children Ages 6-59 Months, Williamsburg, Brooklyn



22,833 MMR doses to children ages ≤18 years, Williamsburg and Borough Park, Oct 2018-May 2019

Legal Challenge

- Five parents challenged the vaccination order claiming it was irrational and violated religious freedom
- On April 18, 2019, Justice Knipel denied motion for an injunction and dismissed their challenge finding:
 - Williamsburg at "the epicenter" of "the most significant spike in incidences in the United States in many years"
 - Petitioners unable to offer better and less restrictive alternative
 - Medical objections not supported by science
- Appellate Division denied TRO on April 30, 2019
- Appellate Division denied Motion for Preliminary Injunction on May 13, 2019

Where are we?

- Since April 9, more than 2000 children in Williamsburg have received the MMR as of May 8
- Yeshivas and Day Cares are complying with exclusion orders and allowing DOHMH to audit them
- As of May 28th, more than 120 people have been issued Notices of Violation for not being immunized or not immunizing their children
 - First cases heard at OATH on May 30th
 - More than 50 withdrawn because proof of vaccine or immunity submitted
- Epi data is starting to suggest an end to the outbreak

MEASLES OUTBREAK: THE CURRENT LEGISLATIVE LANDSCAPE



PARTNERSHIP

Allison N. Winnike, J.D. President & CEO

4 June 2019 The Network for Public Health Law

LEARNING OBJECTIVE

Learn about efforts to make legislative changes in under-immunized states to limit vaccination exemptions and solidify emergency declaration powers



THE IMMUNIZATION PARTNERSHIP

Vision

> A community protected from vaccinepreventable diseases

Mission

> To eradicate vaccine-preventable diseases by educating the community, advocating for evidence-based public policy, and supporting immunization best practices



STATE MANDATORY IMMUNIZATION LAWS

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







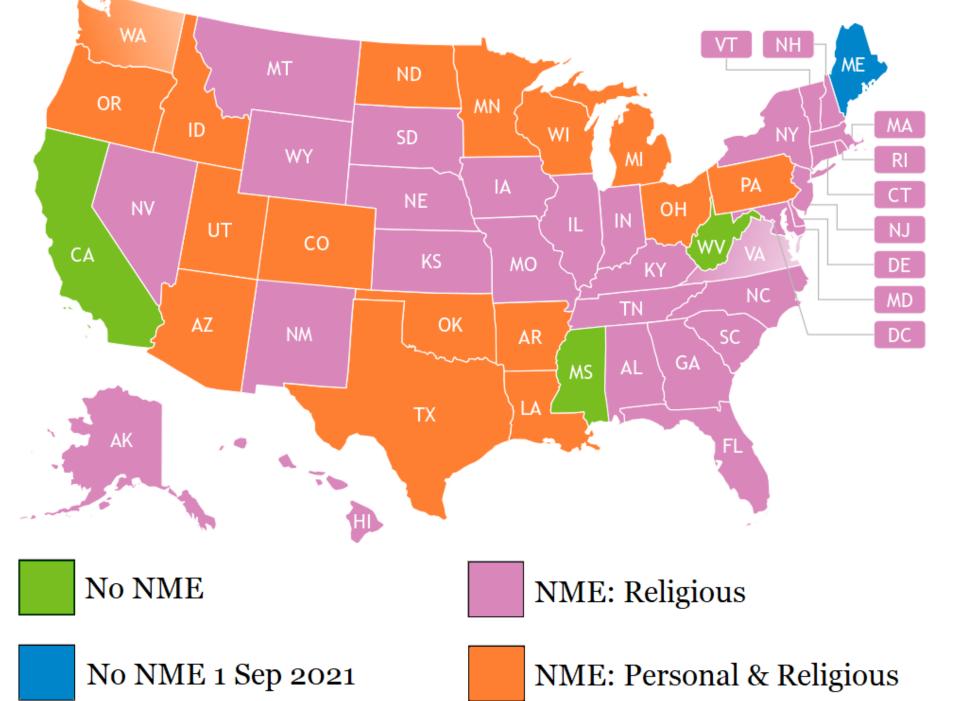
Types of Exemptions

Medical

Non-Medical

Religious

Personal Belief





DATA IS FOR 2016-17 Where the exemptions are TEXAS AND PENNSYLVANIA DATA IS FOR 2015-16 Four Texas counties — including Maricopa, Ariz. (Phoenix) 2,947 Harris County — are among the top 2. Salt Lake, Utah (Salt Lake City) 15 U.S. counties for having 3. 940 King, Wash. (Seattle) kindergarteners with non-medical exemptions for vaccinations. 4. Multnomah, Ore. (Portland) 5. Oakland, Mich. (Troy) 6. Utah, Utah (Provo) 592 Harris (Houston) Tarrant (Fort Worth) 478 Collin (Plano) 10. Macomb, Mich. (Warren) 1 11. Wayne, Mich. (Detroit) 12. Allegheny, Pa. (Pittsburgh) 13. Travis (Austin) 14. Jackson, Mo. (Kansas City)

Source: Public Library of Science Medicine

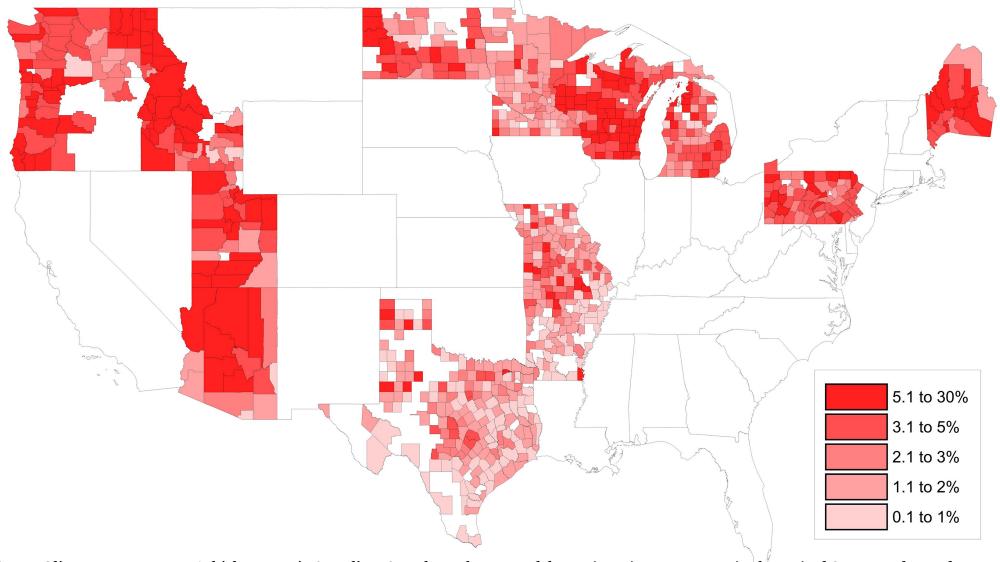
Spokane, Wash. (Spokane)

15.



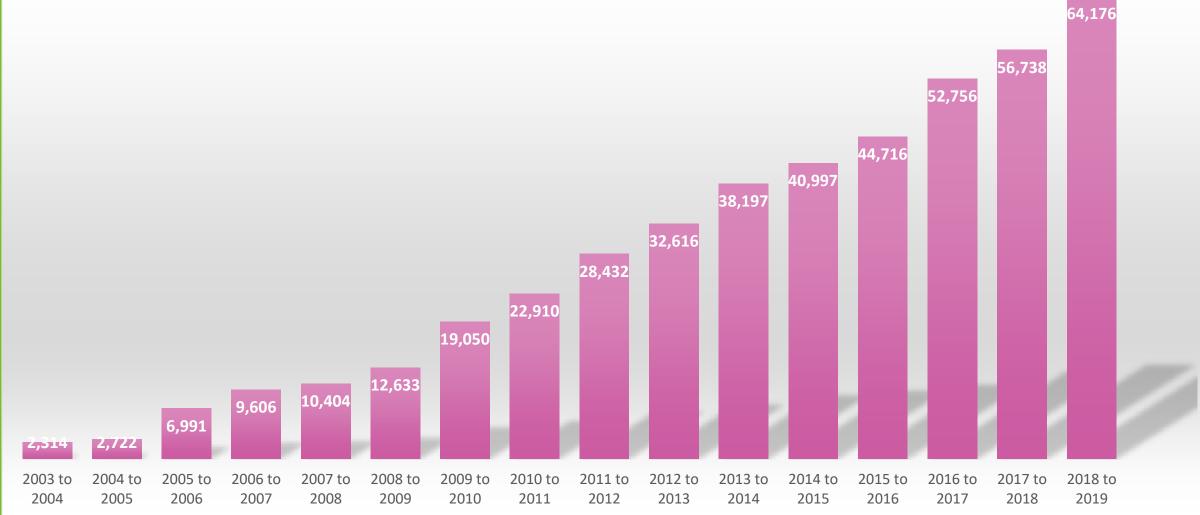
Houston Chronicle

COUNTY-LEVEL NME RATES, 2016-2017



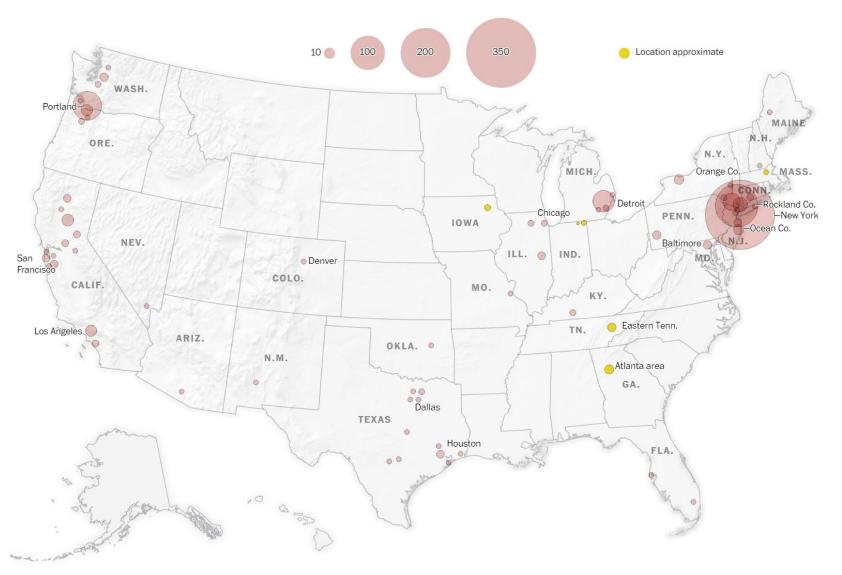


Number of Conscientious Objections in Texas Public and Private Schools





MEASLES CASES BY COUNTY





STATE LEGISLATIVE ACTIVITY





MAINE

- H.P. 586/L.D. 798 removed NME and expanded medical exemption form to include physician, nurse practitioner, or physician assistant judgment
- Passed 23 May 2019
- Signed 24 May 2019
- > Effective 1 Sep 2021



WASHINGTON

- H.B. 1638 removed personal belief exemption to MMR vaccine requirement
 - Personal belief exemptions still available for all other required vaccines
- Passed 24 April 2019
- Signed/partially vetoed 10 May 2019
- > Effective 28 July 2019



CALIFORNIA

- S.B. 276 would authorize California Department of Public Health determine whether the underlying condition cited in a medical exemption meets CDC guidelines
- Passed Senate 22 May 2019
- Governor signaled opposition on 1 June 2019

NEW YORK

- A02371/S02994 would remove religious NME
- Senate Majority Leader indicated there may be enough vote to pass Senate (30 May 2019)
- Governor indicated support

OREGON

- > H.B. 3063 would remove NME
- Passed House 6 May 2019
- Governor agreed to kill all NME bills (including H.B. 3063) in exchange for GOP approval of H.B. 3427, authorizing a new business tax for education on 13 May 2019

COLORADO

- H.B. 1312 would have required NME form filled out in person at a state health department office
- Died 2 May 2019



PUBLIC HEALTH EMERGENCY RESOURCES





PREPARING FOR A

PANDEMIC

An Emergency Response Benchbook and Operational Guidebook for State Court Judges and Administrators

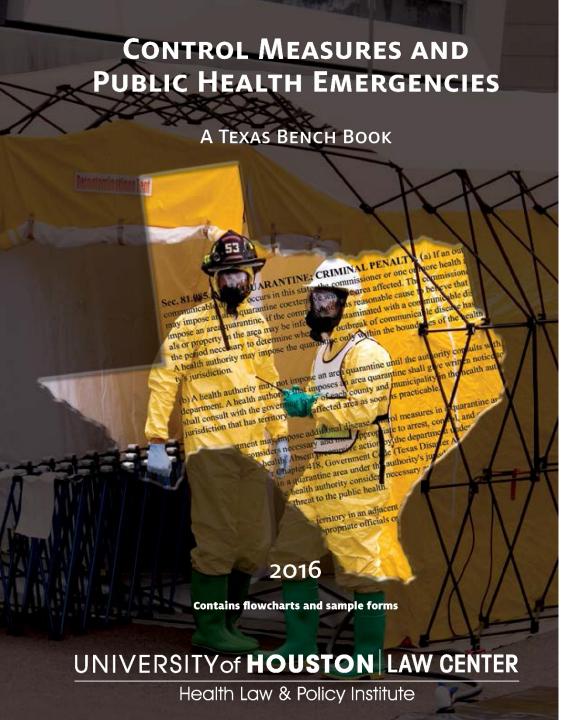




PREPARING FOR A PANDEMIC: AN EMERGENCY RESPONSE BENCHBOOK AND OPERATIONAL GUIDEBOOK FOR STATE COURT JUDGES AND ADMINISTRATORS

Model bench book for states by the Conference of Chief Justices Pandemic and Emergency Response Task Force

http://ncsc.contentdm.oclc.org/cdm/ref/collection/facilities/id/1946



CONTROL MEASURES AND PUBLIC HEALTH EMERGENCIES: A TEXAS BENCH BOOK

Resource for public health officials, judges, district attorneys, and elected officials

http://www.law.uh.edu/healthla w/HLPIBenchBook.pdf



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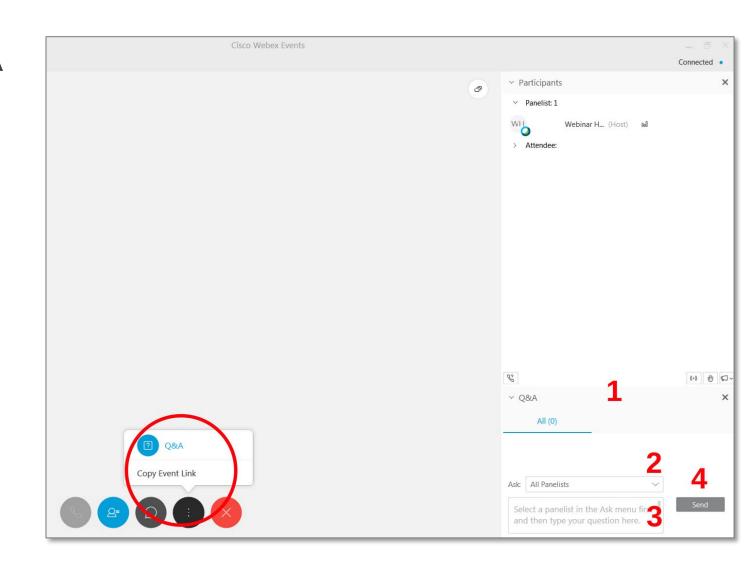






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Advancing the Community Health Worker Workforce through Law and Policy

June 20, 1:00 – 2:30 p.m. EST

2019 Public Health Law Summit

Data Sharing to Improve Community Health October 3-4 | Plymouth, MI







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