Public Health Law 2017: National Trends

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Summit Demographics

GOVERNMENT POSITIONS
- Local: 38%
- State: 60%
- Federal: 2%

J.D.: 57%

DEGREES
- M.P.H.: 21%
- M.D.: 11%
- Ph.D.: 4%
- LL.M.: 3%
- M.P.A.: 3%
- LL.B.: 1%

SECTORS
- Public: 87%
- Private: 13%
Network for Public Health Law

- 5 regions providing local and state support with assistance in:
  - Assessing and explaining public health legal issues and options
  - Helping match experts, resources and tools
  - Conceptualizing new ways to advance a “culture of health” through law

**Major Trends in Public Health Law and Practice: A Network National Report. Fall 2013**

**Legal Innovations to Advance a Culture of Health. Winter 2015**
Major Topics

1. Affordable Care Act: Repeal and Replace
2. Immunizations
3. Federal Common Rule
4. Emergency Legal Preparedness
5. Gun Control
6. Controlled Substances
7. Medical and Recreational Marijuana
8. Nicotine
9. Sugar Sweetened Beverages
10. Preemption
Objectives

- Trends
- Facts
- Impacts
- Forecasts
Using Fake News to Lure Moviegoers
1. ACA
January 20, 2017: Federal agencies can “waive, defer, grant exemptions from, or delay” enforcement of ACA provisions that are too costly. 82 Fed. Reg. 8351

February 27, 2017: “I have to tell you, it’s an unbelievably complex subject. Nobody knew that health care could be so complicated.” NYT, 2/27/17
ACA Repeal and Replacement Strategies

- Continue coverage of dependents through age 26 on guardian’s plans
- Keep prohibitions on insurer caps and rejections
- Repeal the individual and employer mandates
- Retool Medicaid expansion into block grants
- Reassess health care insurance subsidies
- Prohibit federal funding for health coverage of abortions
Repeal of ACA
- Elimination of Public Health Prevention Fund
- Slashing the federal vaccine budget

Enactment of AHCA
- “Health Bill Would Add 24 Million Uninsured but Save $337 Billion,” NYT, March 14, 2017
- Millions stand to lose access to basic health services even as new and existing risks emerge:
  - Communicable diseases threats like Zika
  - Chronic conditions like Alzheimers
  - Injuries related to opiate abuse
Repealing and replacing the ACA is complicated and beleaguered

Intended swift replacement for the ACA may take weeks as the House and Senate continue to debate provisions that are generating considerable consternation

Uncertainty surrounding health reform may lead to instabilities in insurance and health care industries

Public health objectives will inevitably be gutted, derailed, or curbed
2. Immunizations
California SB 277

- Eliminated personal belief and religious exemptions for school vaccination requirements
- Judicial challenges:
  - *Buck v. State of California*
    - Plaintiffs argue SB 277 violates:
      - Child’s constitutional right to education regardless of vaccination status
      - First Amendment Free Exercise Clause
NIH's National Institute for Allergy and Infectious Diseases declared as unethical a proposed Phase 3 “human challenge” study designed to intentionally infect participants with Zika virus to assess the efficacy of potential vaccine.

Robert Kennedy Jr., JD, Prospective Chair and outspoken vaccine skeptic

Healthy young child goes to doctor, gets pumped with massive shot of many vaccines, doesn’t feel good and changes - AUTISM. Many such cases!
Long-standing vaccination requirements have led to meaningful public health achievements in preventing disease outbreaks.

Initial trends in reducing school vaccination exemptions, such as in California, may tamp down outbreaks.

Support for anti-vaccination movements under the current administration could set back childhood [and adult] vaccination rates.
3. Federal Common Rule
Revamping the US Federal Common Rule
Modernizing Human Participant Research Regulations

On January 19, 2017, the Office for Human Research Protections (OHRP), Department of Health and Human Services, and 15 federal agencies published a final rule to modernize the Federal Policy for the Protection of Human Subjects (known as the “Common Rule”). Initially introduced more than a quarter century ago, the Common Rule predates modern scientific methods and findings, notably human genome research.

Research enterprises now encompass vast multicenter trials in both academia and the private sector. The volume, types, and availability of public/private data and biospecimens have increased exponentially. Federal agencies demanded more accountability, research investigators sought more flexibility, and human participants desired more control over research. Most rule changes become effective in 2018, giving institutions time for implementation.

Modernizing Research Regulations
The OHRP last updated the Common Rule in 2005, issuing a proposed rule in 2015 that garnered more than 2000 public comments. National Research Council and National Academies reports also proved influential. Major changes to human subject research protections are noted in the Table.

The Common Rule enhances participant protections while limiting administrative burdens on research entities and investigators. It clarifies what qualifies as human subject research, exempting educational studies,
Major Changes To Come – Jan 2018

- Modernizes human subject research (HSR) provisions
- Clarifies investigators’ oversight responsibilities
- Redefines the nature of research
- Excludes specific activities from the definition of HSR

NATIONAL SCIENCE FOUNDATION
45 CFR Part 690

DEPARTMENT OF TRANSPORTATION
49 CFR Part 11

Federal Policy for the Protection of Human Subjects

AGENCY: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Final rule.

SUMMARY: The departments and agencies listed in this document announce revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and innovation.
Research With Biospecimens & Data

Collector as part of current research
- Standard IRB review and consent requirements

Collector for another purpose (research or clinical care)
- Identifiable
  - Satisfy regulatory exemption criteria
  - Limited IRB review and broad consent
- Nonidentifiable (definition to be revisited periodically)
  - Not "human subjects" research
  - No IRB review or consent

Source: Holly Hernandez Fynch, Health Affairs
Public Health Practice v. Research

(1) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For

The following activities are deemed not to be research

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
The Common Rule modernizes provisions to address current and future research practices

Supports genetic-based research to the extent it does not require consent for secondary studies involving de-identified data or biospecimens

Facilitates research oversight with less onerous IRB roles

Clarifies that public health practice is not HSR

Lacks security safeguards which could lend to data breaches
4. Emergency Legal Preparedness
Reforming Federal Public Health Powers
Responding to National and Global Threats

On January 19, 2017, the day before President Donald Trump’s inauguration, the Centers for Disease Control and Prevention (CDC) published a final rule on communicable diseases. The new rule enhances federal powers to detect, test, apprehend, quarantine, and isolate international and domestic travelers while expanding due process safeguards. Although public health powers should be grounded in science, they also invoke fundamental values of personal liberty and privacy. A decade-long process of modernizing federal rules has been mired in controversy.

Operating under the antiquated Public Health Service Act (1944), the CDC first sought to modernize federal powers in 2005 and again in 2012, but the proposed rules failed to gain public support. The agency issued another proposed rule on August 15, 2016, which attracted 15,800 public comments. Civil libertarians demanded stronger due process protections, while the travel industry raised concerns about regulatory costs in tracing potentially ill travelers.

The CDC’s decision to publish a final rule before the inauguration reflected uncertainty over the incoming administration’s national security policies. These concerns have only been heightened by President smallpox, Ebola). Responding to criticism, the new rule incorporates major changes. Federal powers are primarily reserved for declared health emergencies, as well as a “communicable disease event” with (1) significant potential for disease spread or (2) the possibility of “causing death or serious illness if not properly controlled.” Upgraded prevention measures center on airports and other transit hubs. The agency formalized active screening introduced during the Ebola outbreak, including observation, questioning, and review of travelers’ documents and health records. Airline and other travel industry personnel must monitor and report cases of illness or death.

Under the new rule, federal public health powers now extend to anyone the CDC reasonably believes to be exposed to or infected with specified communicable diseases. Federal public health or border control agents may initially apprehend individuals with direct signs or symptoms (eg, fever, rash, headache, and persistent cough) of illness, and these individuals can be held for as long as 72 hours. The CDC can isolate or quarantine such individuals pending a medical review. The agency must afford confined individuals medical testing, treatment, and other accommodations at the government’s expense.
Major Changes to the Rule

- March 21, 2017 – Control of Communicable Diseases Rule becomes effective.

- Expands and clarifies federal social distancing authority to respond to communicable disease threats

- Broadly defines “ill person” who may be apprehended, isolated, or quarantined

- Evidentiary standard for social distancing powers – reasonable beliefs

- Procedural due process – no neutral decision makers
Emergency Use Authorizations (EUAs)

- January 13, 2017 - Final guidance for industry and other stakeholders on EUAs of Medical Products and Related Authorities
- Authorizes certain emergency uses of unapproved medical countermeasures during emergency circumstances
- Fulfills FDA’s need to efficiently mobilize products that can potentially prevent, treat, cure, or diagnose CRBN threats
CDC’s Control of Communicable Disease Rule ensures efficient and effective responses to emerging threats.

CDC must balance individual rights with protecting communities at risk to avoid legal challenges.

Under FDA’s adjusted EUA guidance, public health authorities may be better equipped to handle emerging drugs and devices in response to threats.

Current federal administration untested and unproven.
5. Gun Control
Guns in the Headlines

Dylan Roof

June 18, 2015

Omar Mateen

June 12, 2016

Nathan DeSai

September 26, 2016
On average 41 gun homicides were committed each day in the U.S. in 2016

Gun Control & the Second Amendment


The question is not “can we remove all guns from U.S. society,” but rather “can we keep certain persons from accessing or using certain guns in certain places?” Professor Stephen P. Teret

McDonald v. City of Chicago, 561 U.S. 742 (2010) ~ 2nd Amendment applies to state and local govts

Access – to stop the flow

Concealment – to limit carrying

Prevention – to curb unlawful use

Detection – to identify presence

Liability – to assess accountability
Routine mass shootings and daily carnage belie a need for stricter firearm regulations

Efficacious regulations are politically non-viable and considered an affront to 2nd Amdt

Relaxing of prior administrations’ gun restrictions for people diagnosed with mental illness marks a dangerous trend
6. Controlled Substances
Still shot from a video taken on September 18, 2016 of a young mother, Mandy McGowen, lying on the floor of a Family Dollar store in Lawrence, Massachusetts after overdosing on fentanyl.

Her 2-year-old daughter tried to wake her while a store employee recorded video.

Image: UsMagazine.com
Federal Comprehensive Addiction and Recovery Act of 2016 (CARA)

- Authorizes over $180 million each year in new federal grant funding to combat the opioid drug epidemic
- Expands
  - naloxone availability
  - prevention and education efforts
  - drug disposal sites
  - treatment and recovery programs
  - prescription drug monitoring

Controlled Substance Regulation

[Map of the United States with states colored to indicate Naloxone Distribution and Good Samaritan Immunity vs. Naloxone Distribution]
Public health and law enforcement responses reflect new approaches

Courts increasingly turning to rehabilitation over incarceration

In January 2017, Seattle-King Count approved 2 safe-injection facilities (SIFs) that permit possession and safe consumption of narcotics

Downside – no guarantees permissive policies will survive federal scrutiny
7. Marijuana
Medical and Recreational Marijuana

States that both a medical marijuana law and have removed jail time for possessing small amounts of marijuana.

Marijuana is legal for adults and is taxed and regulated similar to alcohol; state also has medical marijuana law.
Colorado Experience

- Highest youth rate of marijuana use in U.S.
  - In 2015, 21% of CO youth reported use within last 30 days (although this is down from 25% in 2009)

- Impaired Driving
  - No easy-to-use test
  - Inability to quickly determine whether products in vehicles contain THC

- Largest number of hospitalizations from marijuana use by out-of-state visitors

- First drive-thru marijuana shop license approved in Parachute, CO
California Marijuana Act (Prop. 64)

- Must be at least 21 years old to purchase and lawfully possess up to 1 ounce for recreational use
- Retail stores must acquire a state (and potentially local) license to sell marijuana
- Must be at least 600 feet away from school, day care, or youth center
- “Marijuana Fund:” 15% surcharge on retail price of marijuana
Potential lessened use of opiates in states with legal medical marijuana

Federal administration may (or may not) respect traditional state’s rights

Attorney General Jeff Sessions is outspoken regarding anti-marijuana stances

Legality of medical and recreational marijuana is uncertain
8. Nicotine
FDA Deeming Regulations

April 25, 2014: FDA issued a Notice of Proposed Rulemaking to enable the regulation of e-cigarettes under the Tobacco Control Act

May 5, 2016: FDA promulgated deeming regulation to ban sales to minors and require pre-market review

Aug. 8, 2016: Regulations take effect

Sept. 2, 2016: NYT reports Altria has circulated draft legislation to reverse the deeming regulations
Resulting Litigation

- Suits filed in California, Florida, and West Virginia request court to permanently strike down FDA’s deeming rule.

- Arguments include:
  - Cost-benefit analysis overstates benefits
  - First Amendment violations
  - Costly enforcement
Tobacco and nicotine “wars” collide to diminish use through increased taxes and regulations

FDA authority to regulate e-cigarettes less questionable than its tobacco controls

Future of e-cigarette regulations is sketchy as FDA faces legal challenges and new leadership
9. Sugar Sweetened Beverages
“If governments tax products like sugary drinks, they can **reduce suffering and save lives.**” Dr. Douglas Bettcher, Director WHO’s Dept. for Prevention of Non-communicable Diseases (October, 2016)
SSB Warning Labels

- Passed a trio of ordinances targeting SSBs in June 2015
  - Requires publicly displayed advertising for SSB to display warning label that takes up 20% of ad space
  - Currently being litigated

**SAN FRANCISCO, CA**

**Baltimore, MD**

- Proposed legislation implementing warning labels on sugar sweetened beverages

"**WARNING:** DRINKING BEVERAGES WITH ADDED SUGAR CONTRIBUTES TO TOOTH DECAY, OBESITY, AND DIABETES. **THIS MESSAGE IS FROM THE BALTIMORE CITY HEALTH DEPARTMENT.**"
SSB taxes in local jurisdictions are likely to increase across the nation

With more cities enacting SSB taxes, consumption of SSBs may decrease

There is, however, a cloud in the sky . . .
Preemption: Concept and Reality

- Aversion, displacement, or negation of lower level laws by a higher level of government
  - Congress prohibited smoking on all domestic flights, preempting states from allowing in-air smoking.
  - When the City of Denton passed an ordinance banning fracking, Texas’ state legislature eliminated local control over oil & gas policies.
  - Mississippi’s 2013 legislation barred localities from enacting laws restricting food and beverage portion sizes.
Preemption *Plus* Strategies

- Federal/state law set a “ceiling” forbidding lower governments from creating stricter standards.
- Federal/state laws act as a “floor” preventing lower governments from setting weaker standards.
- Federal law “occupies a field” to completely nullify similar laws at lower levels.
- Federal/state law explicitly prohibits lower level laws on specific topics.

*Plus*

- Direct threats against lower level officials such as fines, loss of liability protection, or removal from office.
- Authorization of private lawsuits against non-complying officials.
- Withdrawals of government funding.
- Broad removal of regulatory authority beyond targeted policy.
- Complete elimination of major restriction of “home rule” authority.
Preemption Plus

- Connecticut localities stripped of their regulatory authority relating to smoking in private workplaces, government buildings, and restaurants
- Florida pro-gun statute displaces local laws and allows penalties or removal against local officials who counter its provisions
- Arizona statute notes that local governments violating state law will lose state-shared revenue until compliance is restored
- Tempe, AZ city council was threatened with loss of its state funds if it pursued a proposed PSST ordinance
Governments increasingly are using preemptive tactics to stifle state or local public health innovations.

Political and judicial fights lie ahead amidst continued shifting priorities on public health agenda.

Tough battle for localities to fight a constitutionally-grounded doctrine.

Communities can lose when local public health innovations are obviated.
Acknowledgements/Final Thoughts

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