SYMPOSIUM

Teaching Public Health Law

GUEST EDITED BY Frances H. Miller

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Letter From The Editor

In recent years, ASLME and JLME have increasingly focused on public health law. Our partnership with the Network for Public Health Law has led to several national conferences and monthly webinars, and we have published more than ever on topical issues in the field, such as Ebola and emergency response planning, concussions and sports, tobacco and obesity issues, and vaccination mandates. As always, we are pleased to be involved with initiatives that connect real-life practice and education, and this supplement is one such opportunity. Together with the Robert Wood Johnson Foundation, this supplement represents a continued effort to stimulate students’ interest in the field by bringing reality-based practice into scholarly education.

Our dear friend Frances Miller guest edits this supplement, “Teaching Public Health Law,” and has brought together six health law professors to design teaching modules on several important topics in public health law. These law professors each completed a six-month fellowship at various public health agencies and then created these teaching modules based on their experiences. These modules are best understood as guides for other professors who want to explore topics in public health law and include suggested readings, assignments, class projects, real-life scenarios, and discussion questions. Topics include bed bugs, vaccine exemptions, regulatory enforcement, disaster relief, and communicable disease. The teaching modules are all published here, but several authors have included additional materials, such as PowerPoint slides, that can be found on our website, aslme.org.

If you are a health law professor — or anyone who enjoys learning about the field — these teaching modules will offer new ways of thinking about and teaching current and existing issues in public health law. We hope these papers inspire a new generation of students to study this rapidly evolving field!

Courtney McClellan
Assistant Editor
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Symposium Articles

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Teaching Public Health Law: Time for a Status Upgrade
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Introducing Law Students to Public Health Law through a Bed Bug Scenario
Jennifer S. Bard
As the scientific evidence emerges, individuals and institutions faced with bed bug infestations find themselves without the legal protections that are available against legally recognized nuisances and threats to the public's health, such as rats or mosquitoes. As a result, they are a good example of how individuals, institutions and municipalities struggle to use the patchwork of public and private legal remedies that are often inadequate to face an emerging threat. This unit is designed to help students gain an awareness that often no one statute or case can be invoked as a complete solution to a legal problem, as well as the inherent limits of legal solutions in addressing public health problems that stem from poverty and powerlessness.

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Personal Beliefs Exemption from Mandatory Immunization of Children for School Entry
Alexander M. Capron
Requiring immunization for school attendance greatly reduced morbidity and mortality in children over the past seven decades but is now highly controversial. This two-part exercise on the implementation of a “personal belief” exemption allows students to examine constitutional questions as well as legislation and regulations as they affect public health and school officials.

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Including Public Health Content in a Bioethics and Law Course: Vaccine Exemptions, Tort Liability, and Public Health
Mary Crossley
Incorporating public health content in a bioethics and law course can prompt rich discussions. This set of materials on mandatory vaccinations, nonmedical exemptions, and potential tort liability for nonvaccination explores the roles of public health law and tort law in advancing social goals and protecting individual rights and interests.

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Improving Regulatory Enforcement in the Face of Inadequate Resources
Sharona Hoffman
This exercise is designed to focus students’ attention on the challenges of regulatory enforcement. The case example is drawn from Oregon’s regulation of in-home care agencies (IHCA). Students are asked to formulate suggestions for enhancing compliance with IHCA regulations in the absence of additional funding. The author includes her own suggestions, which she developed during her fellowship.
Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine, and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of JLME.

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Disaster Relief: Restricting and Regulating Public Health Interventions
Browne Lewis

The information contained in this teaching module and the accompanying PowerPoint slides is appropriate for use in a survey public health law course or seminar. The purpose of this lesson is two-fold. The first objective is to provide law students with an overview of the authority public health agencies have to set and enforce policies necessary to keep the population healthy. The second objective is to inform law students about the legal constraints courts have placed upon the actions of those agencies. The module ends with a project designed to give law students the opportunity to apply the law to a “real-world” situation.

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Public Health Control Measures in Response to Global Pandemics and Drug Resistance
Polly J. Price

These teaching materials provide problem-based exercises exploring the specific powers of governments to implement control measures in response to communicable disease. Topics include global pandemic disease and, in the United States, legal issues in tuberculosis control.
INTRODUCTION
Teaching Public Health Law: Time for a Status Upgrade
Frances H. Miller

Public health law has never enjoyed particularly high standing in the curricular pecking order of most law schools; too few legal academics understand that more advances in human health and well-being have stemmed from implementing population-wide health measures, like vaccination and sanitation improvements, than from administering medical care to individuals. They often fail to recognize — disregard, if you will — public health law as a crucially important tool in the arsenal of measures to improve the general health and well-being of populations. Schools of public health, on the other hand, have been much more keenly aware of public health law’s importance to social welfare, and have thus taken it more seriously in the classroom.1 But they have generally lacked the ability to help agencies bring legal tools to bear on public health problems because their students are not generally lawyers.

The Robert Wood Johnson Foundation (RWJF), “the nation’s largest philanthropy dedicated solely to health,”2 decided in 2010 to make improving public health law and its practice a major focus of its philanthropic outreach. It recognized that beleaguered and underfunded local public health agencies often lack the sophisticated expertise to tackle complex problems, and that they rarely have resources sufficient to do more than react to public health problems reflexively as they flood in (sometimes literally). To help ameliorate those problems, RWJF established the Public Health Law Network to provide a one-stop website devoted to making public health law expertise and policy accessible to other lawyers and the general public.3

The Foundation also launched a number of fellowship programs designed to enrich and enhance the teaching and practice of public health law, including the Scholars in Residence Fellowship Program (SIR), which I had the good fortune to direct during 2013. The Foundation established SIR because it realized that public health law teaching in the legal academy needed a dose of reality-testing, which could be accomplished in conjunction with providing high-level scholarly help to public health agencies whose legal resources have long been stretched thin by budgetary pressures. RWJF also recognized that public health law needed a status upgrade within academe, so that students (and faculty) would perceive careers in devising, implementing, and protecting public health initiatives as an attractive practice opportunity.

Thus was born the idea of giving a small number of master teacher/scholar law professors six-month fellowships, which would include embedding themselves physically in the public health agencies of their choice for at least a month. There they would work on a pressing legal issue agreed upon between themselves and their agencies, and at the end of six months, the fellows would produce reports designed to “make things better” concerning those problems. In the process they would acquire first-hand knowledge about the way public health law actually plays out in practice, and then bring that wisdom back to enrich their students’ classroom learning and stimulate their interest in public health sector practice.

The SIR program worked out splendidly, and the six outstanding law professors chosen for the fellowships4 exceeded our expectations for enthusiastic partnering with their agencies to work on pressing issues — some of them long-term problems and others of more recent origin. The agencies would probably have lacked sufficient professional staff to tackle these difficulties so thoroughly and successfully on their own, and were correspondingly grateful for the scholarly assistance.

Frances H. Miller, J.D., is a Visiting Professor of Law, William S. Richardson School of Law, University of Hawaii at Manoa, and Professor Emerita at Boston University School of Law.
The projects ranged from bedbug eradication and cross-border control of infectious tuberculosis, to regulating small cigars and in-home care agencies, to proposing agency collaboration with not-for-profit hospitals to fulfill the Affordable Care Act’s community health assessments requirement, to drafting ambulatory care improvement legislation and health officer orders requiring medical worker vaccination or masking during flu seasons. In some ways the most rewarding — and somewhat surprising — aspect of these widely varying alliances has been the continuing relationships forged between many of the fellows and their agency counterparts, which persist more than a year after their formal relationships ended.

As a by-product of their agency experiences, the SIR Fellows also produced the public health law teaching modules published in this supplement to the Journal of Law, Medicine & Ethics. Their materials reflect not only the varying experiences of their authors interfacing with the way public health law is actually practiced, but also the insights the fellows gained about better teaching through reflecting on what they learned “at the coal face.” RWJF made producing these modules — which include background materials, problem exercises, and mini teaching manuals, as well as (in some cases) explanatory PowerPoint slides — a requirement of the SIR Fellowships. The Foundation is dedicated to raising the profile and teaching of public health law in the nation’s law, medical, and nursing schools, as well as in its schools of public health — and in any other educational venues where students can be imbued with a passion for staying involved with the constantly evolving and often fascinating ways in which law can be used to promote better population health. We hope these teaching materials will advance that objective.

On the theory that different students (and professors) learn (and teach) in different ways, and that all of us can probably benefit from looking at improving public health law teaching through different lenses, no attempt has been made to impose a common organizational form on these modules. The diverse materials reflect both the personalities and teaching styles of their authors, as well as — in most cases — the individual projects on which they were engaged with their agencies.

On the theory that different students (and professors) learn (and teach) in different ways, and that all of us can probably benefit from looking at improving public health law teaching through different lenses, no attempt has been made to impose a common organizational form on these modules. The diverse materials reflect both the personalities and teaching styles of their authors, as well as — in most cases — the individual projects on which they were engaged with their agencies.

belief exemption from mandatory vaccination, and the other examining the possibility of tort liability for parents who fail to immunize their children. We hope they inspire you to think more broadly about what might constitute effective teaching, and to experiment with different ways of getting students engaged with the subject matter of public health law.

Acknowledgement
Support for the Scholars in Residence fellowship program was provided by the Robert Wood Johnson Foundation.

References
4. Professors Jennifer Bard of the University of Cincinnati College of Law, Professor Alex Capron of the University of Southern California Law School, Professor Mary Crossley of the University of Pittsburgh Law School, Professor Sharona Hoffman of Case-Western Reserve Law School, Professor Browne Lewis of Cleveland State University Law School, and Professor Polly Price of Emory Law School.
Introducing Law Students to Public Health Law through a Bed Bug Scenario

Jennifer S. Bard

Learning Outcomes:
After completing this unit students will:

1. Be able to describe the sources of legal authority that apply to dispute between a landlord and tenant over a public health nuisance — specifically a bedbug infestation
2. Identify how provisions in a contract affect a tenant’s options when confronted with a public health nuisance
3. Differentiate between a statute which gives cities the power to require bed bug abatement and one that requires such abatement.
4. Describe the role of the judicial system in a dispute governed by a contract.

Method of Assessment:
Students will be asked to draft a letter to a client advising her of her legal options (and obligations) in the face of a bed bug infestation in her rental apartment.

Materials:
Primary Source Packet-
Chicago Bedbug Ordinance
NYC Bedbug Protocol

Articles

Introduction
About Bed Bugs
Bedbugs are tiny, wingless insects which feed on mammal blood and leave behind painful, itchy sores. Although they can live in other settings, they are most commonly found in warm, dark places inhabited by humans, like beds. After being absent in the United States for over 60 years, thanks to powerful pesticides, bedbugs (Cimex lectularius), have returned in force and are present in every state and nearly every city. For reasons not entirely understood, bed bugs have developed resistance to traditional pesticides such as Permethrin and are therefore difficult to control. Although commonly believed to be associated with dirty housekeeping and associated with substandard housing, bed bugs are equally likely to be present in five-star hotels as they are in homeless shelters. They have come to infest schools, dorms, court houses,
nursing homes, and mass transportation systems. Yet because they have been held in check by pesticides, there is very little contemporary research on whether they are qualify as a legally recognized “nuisance” let alone an actual threat to the public’s health.

As the scientific evidence emerges, individuals and institutions faced with bed bug infestations find themselves without the legal protections that are available against legally recognized nuisances and threats to the public’s health, such as rats or mosquitoes. As a result, they are a good example of how individuals, institutions and municipalities struggle to use the patchwork of public and private legal remedies that are often inadequate to face an emerging threat. This unit is designed to help students gain an awareness that often no one statute or case can be invoked as a complete solution to a legal problem, as well as the inherent limits of legal solutions in addressing public health problems that stem from poverty and powerlessness.

About Lubbock
This unit considers legal issues in the setting of Lubbock, Texas, a city of approximately 212,365 people, located in West Texas. Although the region is one of the top cotton growing areas in the country, there are areas in the city where people live in the kind of urban poverty seen in other cities of similar size. As the home of Texas Tech University, Lubbock also has a very transient population with a large number of apartment buildings and rental property.

Addressing Bed Bug Issues in Apartments
Bed Bug infestations in apartments raise serious legal issues because they often involve situations where the tenant has had no role in causing the infestation. As the Texas A&M Agrilife Extension service explains, “If one apartment is infested, adjoining units (left side, right side, above and below) should be assumed to be infested unless shown otherwise through inspection or monitoring.”

Problem Scenario
A friend of yours who is a graduate student comes to you with a problem. She recently moved into the Willow Creek apartment complex. After living there about a week, she started waking up with blood on her sheets from red, itchy welts on her arms and legs. On closer inspection, she found tiny bugs, no bigger than an apple seed. After looking them up on Google, she recognized them as bed bugs and notified her landlord. The landlord is not only willing to bring in an exterminator, he is insisting on doing so — at her expense. She wants to know if she really is responsible for the cost. She also wants to know if she can break her lease. You ask her to bring the lease and any other written information from her landlord and you will go over them with her.

The next day she comes to see you with the Texas Apartment Association Bed Bug Addendum that she signed on moving in. After reading the addendum,

- What questions would you ask her?
- What laws apply to her situation?
- What aspects of Texas Law are favorable to her situation?
- What agencies can she go to for help?
- How would her situation be different if she were in Chicago?
- In New York?

Sources of Law
Two major sources of law in the United States can be used to require a landlord to eradicate a bed bug outbreak: private law suits between landlords and tenants and inn keepers and guests, as well as public actions taken against property owners by the City, court cases, and statutes. The laws that apply to housing in general and bed bugs in particular vary considerably from state to state. This unit focuses on the laws of Texas because it is one of the few states that specifically names bed bugs in its nuisance statutes.
A. Covenant of Quiet Enjoyment
In Texas, a landlord who rents an apartment is promising that the apartment is habitable and fit for living for the length of the lease.\textsuperscript{14}

B. Torts
A “Nuisance” action can also be brought under Tort theories of Negligence.

C. Public Nuisance
Texas gives individual municipalities authority to address public nuisance issues within their own geographic borders,

“The Texas Department of State Health Services (DSHS) will refer public nuisance complaints to municipalities and counties with local health departments or code enforcement officials. DSHS will respond to public nuisance complaints in areas of the state that do not have a local health department or code enforcement officials.”\textsuperscript{15}

D. Contracts
Another source of legal remedy is found in the contract between the landlord and tenant. In Texas, most apartment leases are modeled on the one created by the Texas Apartment Association. Under the general provisions of Texas property law, a tenant has the right to leave or pay for treatment and sue for reimbursement in small claims court, but very rarely can a tenant withhold rent in Texas.\textsuperscript{16} The Texas Apartment Association (TAA) has recently added an addendum specifically related to bedbugs.\textsuperscript{17}

As Richard Alderman, Associate Dean of the University of Houston Law Center and director of UH’s Center for Consumer Law explains, the addendum is “not tenant friendly” in that it “tries to shift the burden onto the tenant by limiting the amount of time that a tenant has to report bed bug infestation after moving in and then further limiting the landlord’s responsibility to eradicate bed bugs once the tenant has agreed it was not infested at move-in.”\textsuperscript{18}

One of the realities of this situation is that lack of money means lack of choices. So while an individual with the ability to pay for a clean and safe apartment would have a choice about whether to sign a lease with one landlord or another, someone without these resources has to take what he can get.

Powers of the Local Health Department\textsuperscript{19}
Given the limited ability of individual tenants to seek redress if their apartments become infected, the most likely source of help is the local health department. Health Departments play the role of intervening when the ability to control a potential hazard is beyond the ability of an individual and poses a considerable danger to the community.\textsuperscript{20} This is the rationale for vaccination clinics and publically funded treatment for communicable diseases like TB.\textsuperscript{21} The risk posed to all citizens by bed bugs is of a similar nature, if not of life-threatening magnitude. The power of a local health department to require remediation is strongest when victims are either tenants or they are individuals under state protection.

Whether or not a tenant has agreed to assume the cost of bed bug eradication does not affect the City’s ability to issue citations. The two areas of law are unrelated. Given reasonable suspicion of infestation and the risk that if one apartment is infested, others will be as well, a tenant cannot prevent the city from inspecting the premises any more than a landlord can.\textsuperscript{22}

While legally it is possible for the city to respond to a health hazard in a private home, for the most part this only happens when the inhabitants are under special protection, such as children (and even more so foster children), or when the health hazard extends beyond the boundaries of the property to cause a risk to others. For example, if a private home owner did not fix a broken pipe on her property and allowed sewage to run into her neighbors’ homes, the City could intervene.\textsuperscript{23}

Texas Law Specifically Identifies Bed Bugs as a Nuisance
Provides that “the presence of ectoparasites, including bedbugs, lice, and mites, suspected to be disease carriers in a place in which sleeping accommodations are offered to the public” is a “public health nuisance.”\textsuperscript{24}

Chicago Bed Bug Statute
\textsuperscript{4-4-332 Bed Bugs}
a. It is the responsibility of every licensee under this title 4 to provide pest control services when bed bugs are found on any licensed premises. The pest control services shall be conducted by a pest management professional as many times as necessary to totally eliminate the reported bed bug problem. Every licensee shall maintain a written record of the pest control measures performed by the pest management professional on the licensed premises and receipts and reports prepared by the pest management professional relating to those measures taken. The record shall be open to inspection by the departments of health, buildings, and business affairs and licensing.

A Plaintiff alleging a claim of constructive eviction must prove that:
1. the landlord intended that the tenant no longer be able to enjoy the premises,
2. the landlord acts in a manner that substantially interferes with the tenant’s right to enjoy and use the premises,
3. the landlord’s act permanently deprives the tenant of the use and enjoyment of the property, and
4. the tenant abandons the premises within a reasonable time after the act occurs.

Working with Other Regulatory Agencies
Another source of redress for those whose living quarters are infested with bed bugs comes when the premises are regulated by state or federal housing authorities.

State Housing
Section 8

HUD Less Supportive of Eradication
HUD recently changed these rules in a way it perceives as shifting more of the burden to tenants. This perception is supported by the fact that the changes were brought by the “direct urging” of the National Multi Housing Council, a trade organization of property owners. The NMHC claimed that “it created confusion about best management practices, hamstrung the efforts of owners and property managers to prevent infestations and failed to meaningfully address the financial issues to the owner and resident related to recurrent infestations.”

State-Regulated Facilities
Michigan has been a leader in developing laws to protect individuals in state-regulated housing from bed bugs. Texas, like Michigan, has specific jurisdiction over residences and facilities that accept Medicare and Medicaid funding. This includes “nursing homes, hospice residences, hospitals, adult foster care, homes for the aged, child foster care, and child residential centers. Additionally, Michigan regulates agricultural labor camps, campgrounds, child care facilities.” All of these facilities require a state license which could be contingent on control of nuisance conditions like bed bugs.

Looking at the Box from All Angles — Solving Bed Bug Problems by Using Social Media to Bring Pressure on Landlords, Hotels, and Motels to Eradicate Bed Bugs
The law is not always the best instrument for solving nuisance conditions. Social media and the Internet already play an important role in alerting the public of motels and apartments which have experienced bed bug infestation. In addition to internet social media, the TV, radio, and print media might be interested in reporting inspection results for bed bugs as they now do for restaurant inspections. This would create economic pressure on business which rely on the public making a choice to frequent their establishment or not. A good example of this in Lubbock is the Thursday, “Food for Thought” segment on local TV and in the newspaper.

Conclusion
Bed Bug infestation has become a common issue at all levels of housing in the United States. Although Bed Bugs have not yet been categorized as a direct threat to human health, this is likely due to their recent re-emergence as they become resistant to the pesticides that used to control them. As a result, there is a dearth of scientific research on their ability to transmit blood-borne disease. At best, however, they are a serious nuisance and inflict painful and itchy bites. Yet unlike the laws that protect tenants and consumers from other nuisance conditions, the laws protecting the rights of landlords and tenants is often unhelpful because it was not drafted to address this specific hazard. This teaching unit has considered common scenarios where tenants and landlords would seek legal advice. It highlighted categories of legal redress that may be available, depending on the specifics of state law. It also considered strategies when the law has not yet evolved to provide a remedy.

Acknowledgment
With special thanks to Professor Fran Miller — once a St. Hilda’s girl, always a St. Hilda’s girl.

Support for the Scholars in Residence fellowship program was provided by the Robert Wood Johnson Foundation.

References

3. Id. (Doggett et al.), at 164-165.


5. See J. Caan, “Will-Kil Pest Control Advises Travelers to Take Precautions Against Bed Bugs this Spring Travel Season,” Mequon Now, March 27, 2015, available at http://www.mequnonnow.com/userstoriesubmitted/29781701.html (last visited June 1, 2015) (“Because these pests are not associated with uncleanliness or poor hygiene, they are just as likely to show up at a five-star resort as they are a roadside motel, which means all travelers need to be diligent in taking precautions to avoid bringing home bed bugs.”).


19. See, e.g., Tex. Health & Safety Code § 341.012 (West 2013). The Texas statute for Abatement of a Nuisance provides that:
(a) A person shall abate a public health nuisance existing in or on a place the person possesses as soon as the person knows that the nuisance exists.
(b) A local health authority who receives information and proof that a public health nuisance exists in the local health authority’s jurisdiction shall issue a written notice ordering the abatement of the nuisance to any person responsible for the nuisance. The local health authority shall at the same time send a copy of the notice to the local municipal, county, or district attorney.


22. See, e.g., N.H. Rev. Stat. § 540-A:3. In New Hampshire, the statute dictates that a tenant cannot refuse the landlord access to the premises if the landlord is required to evaluate whether bedbugs are present. Id.


26. Id.

27. Id.


Teacher's Guide

I. Background

Public health law courses typically focus a good deal of attention on two related topics: the duty of government agencies to control the spread of communicable diseases and their use of the police power to do so. While governments sometimes take forceful actions in responding to disease outbreaks, they can also act to prevent their occurrence. Indeed, one of the great triumphs of public health in the 20th century was the development of vaccines and their widespread use, which seemed on course to relegate many formerly crippling or deadly diseases to the history books. Particular success occurred with vaccinations against childhood diseases such as polio, smallpox, and measles, outbreaks of which once routinely closed schoolrooms, playgrounds, and community swimming pools. By the last quarter of the century, completion of an elaborate schedule of immunizations was not merely the standard in pediatric practice but an official requirement for school enrollment. As a result, the range of communicable diseases that had once terrified parents had become threats to be feared only in memory.

From the origin of vaccines in the 18th century, a few people have objected to the procedure as unnatural or unacceptably risky, especially since it is performed on otherwise healthy people; likewise, some people object to all government mandates regarding personal life. These objections have been a part of general debates among the public and in legislative chambers about the correct balance between individual liberty and state action to protect the health of the community. This tension can be expressed in terms of benefits and harms: in a society with a high rate of vaccination, any particular child would be better off not taking on the very small risk of injury from being vaccinated, but if everyone acted that way, then all would be much worse off, as the risk of coming down with a vaccine-preventable disease would go from miniscule (as it is when the community enjoys the “herd immunity” that a high vaccination rate provides) to substantial (as it was pre-vaccines).

The result is that, to overcome the “collective action” and “free rider problems,” all states have compulsory school immunization laws; each state decides which vaccines to require, based on recommendations from the CDC, acting with guidance from the Advisory Committee on Immunization Practices. Children with medical contraindications to immunization are exempted. In response to parents with religious objections, all states save Mississippi and West Virginia grant exemptions to those who claim (with varying degrees of required affirmation and documentation) that their religion prohibits vaccination. In addition—perhaps to foreclose a potential Establishment Clause objection that particular religious beliefs were being privileged—20 States allow parents with “moral” or other personal objections to vaccination to register their children for school entrance without providing evidence that the children have completed the required immunizations.

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Although religious and personal belief exemptions from compulsory immunizations have been filed for only a small percentage of school-age children, the number has been rising in recent years and in some communities has reached levels high enough to eliminate herd immunity for a number of childhood diseases. The anti-vaccination forces were given a big push by a 1998 article in The Lancet in which Dr. Andrew Wakefield, a British surgeon and researcher, produced research results showing a link between the MMR (measles, mumps, and rubella) vaccine and autism and bowel disease. Subsequent investigations not only failed to confirm Wakefield’s findings but resulted in his being struck off the medical register and the withdrawal of the 1998 article by The Lancet, whose editor stated that it had been “deceived” by Wakefield into publishing his “utterly false” paper. Independent studies by the Institute of Medicine (part of the National Academy of Sciences) have concluded that the purported link between vaccination and autism spectrum disorder lacks any factual basis.

Nonetheless, vocal critics (including a few celebrity parents and the occasional medical skeptic) remain and the rates of vaccination-refusal have risen, ironically in some affluent, middle-class neighborhoods where the high rate of residents with college and advanced degrees is usually reflected in a high level of acceptance of scientific data (on issues like evolution, climate change, etc.). When an imported case of measles turns up in such a community, the disease — which is highly contagious — can spread widely and quickly due to the suboptimal local rate of vaccination. Several such outbreaks in recent years have led to calls to tighten or remove the exemptions to the required vaccinations. This exercise deals with the changes that took effect in California in 2013, restricting the “personal belief exemption” to childhood immunization requirements; to bring the issue up to date, several additional sources are provided regarding another measles outbreak in 2014-15 that led to the adoption of a more restrictive statute in June 2015.

The question for students is: To what extent should the state allow parents to make choices about vaccinating their children against communicable diseases that can cause injury or even death?

II. The Exercise: A Review

I conducted this two-part exercise in my spring 2015 public health law class. It proceeded as follows.

1. I provided students with a description of the issue at “Stage 1,” including a bill pending in the California legislature as of August 20, 2013, and some background articles, and a list of questions to consider. The students could pick which of five groups they would represent in analyzing the pending law, and the presentations were made to the whole class.

2. The exercise can be run in a number of different ways, depending on the size of the class and the pedagogical and assessment objectives — i.e.,

   • students can just present their analysis orally or also submit written analyses;
   • the exercise can be used to promote teamwork or to allow the students or instructor to assess individual abilities;
   • the analysis can be assigned as homework or undertaken as an in-class activity, etc.;
   • a sixth group of students can play the role of the legislative committee developing the bill, who would ask questions of the each student (or group of students) representing a particular client at the “hearing.” The students in this role would then present an explanation of which arguments they found most persuasive; if the exercise is being evaluated based on a written product, they could write up a “committee report” to accompany the legislation.
3. The students were very creative in formulating their positions. Here are a few of the points I expected them to raise:
   a. Relative v. Absolute Risk: Some of the rising level of vaccine-refusal is based on genuine belief on the part of some parents that the choice is most protective of their child’s welfare. In a community with a level of vaccination high enough to create herd immunity, this may well be an accurate appraisal of the risk of getting vaccinated versus not, although the probability of suffering harm from getting vaccinated remains very small.
   b. The Tragedy of the Commons: If everyone follows this rationale, then herd immunity is lost and all the children are at much higher risk.
   c. The Unfairness of Free Riding: Leaving choice in individual hands may still result in an adequate level of immunity, but children whose parents exempt them from vaccination are exploiting the community-oriented acts of others to gain protection without contributing to the achievement of the herd immunity.
   d. Collective Action: Is it legitimate for the state to force children to get vaccinated, not because any one unvaccinated child poses a measurable risk to other children (principally, those too young to be vaccinated and those for whom vaccination is contraindicated, such as children with compromised immune systems) but to counteract the problems described in b. and c. above?
   e. How Some “Exemptions” Arise: Some parents do not object in principle to vaccinating their children but simply haven’t completed the course of recommended vaccinations. It is in the interest of school administrators to accept all the children who come to enroll, since payments from the state to schools are based on the number of students present in their classrooms. When faced with a child who is ready to enroll but who lacks the required vaccination documentation, the school official can either instruct the parent to come back after obtaining the documentation or can tell the parent that the child can be enrolled if the parent fills out a form exempting the child from the requirement based on a “personal belief.”
   f. The Overt Rationale for the Change in the Law: A.B. 2109 would change the personal belief exemption as then applied by requiring a parent (or guardian) who has not had his or her child vaccinated to provide a health care practitioner’s “signed attestation” that the practitioner has given the parent “information regarding the benefits and risks of the immunization and the health risks of specified communicable diseases,” as well as a statement by the parent indicating that he or she has received this information. The ostensible reason is to ensure that parents (and guardians) are aware of the scientific and medical evidence regarding vaccinations, in case their refusal was based on ignorance or misunderstanding of the risks and benefits.
   g. Behavioral Economics: Under the existing law, filing a personal belief exemption is a fairly costless act: it simply requires a signature (and, perhaps, a willingness to aver something that isn’t the case). Indeed, prior to the recent development of a registry accessible to schools, the exemption was even used by parents who do not actually object to vaccinating their children but who simply did not bring the necessary documentation when they came to register their children for school. Thus, the requirement that a parent go to a health care provider to receive information about immunization can be seen in behavioral as well as cognitive terms: it raises the cost of refusing to allow vaccination because that — like getting the child immunized — now also requires a trip to the health care provider. (Note that this effect would be lessened if a school has a nurse on site who could provide the required educational information without necessitating a trip to a pediatrician or clinic.)

4. A major point of an exercise like this, with role-playing, is to have the students understand that reasonable arguments can be made for and against the proposal. Further, some of the arguments for a conclusion made by one group may be inconsistent with other arguments for the same conclusion made by another group. Can legislators who favor that conclusion use these varying reasons in supporting the bill (as an instance of the “mud-
dling through” described by Yale political scientist Charles Lindblom)?

5. The exercise is designed to be done in two parts; I did it in two successive classes. Stage 2 is a shorter assignment, with less reading and a shorter list of questions for the students — still representing the same groups as during Stage 1 — to consider. I ran it as a general discussion, rather than as a legislative hearing. Some of the ideas that should emerge:

a. Executive Power: In recent years, when signing legislation into law Presidents and Governors have taken to issuing “signing statements” in which they announce their reading of the statute.
   • If the chief executive has discretion in executing the law in question, would announcing his or her intention to apply the law narrowly be nothing more than making clear how the law will be enforced?
   • What if the signing statement purports to add a provision absent from the text of the statute?
   • Should other officials or the courts give any weight to such statements?
   This issue has not been well addressed but the consensus seems to be that such statements cannot literally amend a statute.

b. Religious Exemptions: When he signed A.B.2109 into law in September 2012 Governor Brown issued a statement to the State Assembly in which he said an extra exemption would be added to the form issued by the Department of Public Health to implement the new law: people whose religious beliefs preclude vaccinations would not be required to seek a health care practitioner’s signature on their exemption forms.
   • Is such an exemption in line with the purpose the legislature had in amending the immunization exemption process? (No, since the legislature intended to reduce the number of exemptions.)
   • Is the broader exemption necessary to protect the rights of persons with religious objections to vaccinations under the Free Exercise Clause of the First Amendment?
   • At the same time, would it create a privileged class of persons under the Establishment Clause? This is the classic tension regarding religious exemptions to public health practices, but Mississippi is the only state whose highest court has held a religious exemption unconstitutional because most parents would not qualify for it (unless they joined a church with such a doctrine).

c. Competing Pressures on Agencies: Should the appointed director of the department follow his own reading of the statute or the instructions of the governor? The answer would seem to be, “He should do what he is told to do if he wants to keep his job,” but students ought to think about the pressures from the public health professionals within the department (who supported the bill to make exemptions more difficult); these might push a director to advocate with the governor for some solution that would better reflect the legislature’s objective and the health interests of the public — but that would also not cause the governor to lose face.

d. Challenging Executive Action: Students should also think about the topic in terms of the litigation that might arise with either solution, which is different from thinking about the issues solely as matters of abstract principle. Sometimes, it is not obvious how a particular person would have the sort of interest that is required for standing to challenge a governmental act. So, if the department of public health issues a form lacking the language that the governor had instructed it to include:
   • What kind of action could a person with a religious objection to vaccinations bring, and would its likely success differ from a suit brought had the governor not made his statement?
   • Could such a person successfully seek to have the form enjoined because the department did not include the language ordered by the governor?
   • Would a religious objector’s cause of action have a better chance of success by challenging a school’s refusal to enroll his or her child based on the absence of a health practitioner’s signed attestation on the exemption form?

The converse hypothetical is even more interesting — that is, if the form issued by the department did contain the additional exemption for religious objectors as promised by the governor — what action might someone who objected to that added exemption take?
• Could a legislator sue to enjoin the use of such a form because it departed from the language specified in the statute?
• Could the department claim that the governor was “not amending the statute” but merely including language in the form that he believed was needed to make it constitutional?
• Doesn’t it seem doubtful that a parent who had complied with the law by getting her children vaccinated could not sue a school for admitting students whose parents had neither done so nor produced an attestation of “education” by a health care professional?

Even the parent of a child who cannot be vaccinated for medical reasons and who is therefore placed at risk by the presence of unvaccinated schoolmates probably could not succeed in court, though that is a closer case. But perhaps a school district that believes the additional exemption is neither wise nor authorized by statute could issue its own form without the religious exemption.

• How should a court rule on a suit brought by a parent with a religious opposition to vaccination on the ground that only the state department of public health is authorized to issue the forms and the form that it had issued included the exemption from providing a practitioner’s attestation?
  e. Compromise: The same issues would face the five groups represented by the students as regards the form issued by the department in October 2013. Some may think the form is wrong because it contains an exemption not specified in A.B. 2109; while others may object that the exemption is narrower than the one that the governor promised. Again, the students can examine this from the perspective of “what is the right policy?” or “who would prevail on what set of facts in litigation?”

6. Another outbreak of measles, which began in December 2014 among children who had been to Disneyland and spread from California to a number of other states, serves as a reminder that the new law did not put an end to vaccine refusal; indeed, the number of cases of measles — a disease that had been declared eliminated in the U.S. in 2000 — reached a 20-year high in 2014. As the Disneyland measles cases continued to spread in the first months of 2015, legislatures in a number of states took up bills that would have ended all non-medical exemptions for school enrollment as well as bills that sought to narrow the exemption or place burdens on it, as A.B. 2109 had done. While many of the most restrictive bills failed in the face of strong opposition from vaccine opponents, in California S.B. 277, which eliminates the personal and religious exemptions, was enacted despite heated opposition by some parents’ groups and signed into law on June 30, 2015. This provides a starting point for further discussion of what steps a state may — and should — take, at what cost to liberty versus to health, in trying to achieve the particular public health goal of avoiding vaccine-preventable childhood infectious diseases.

Materials
Stage 1
1. Exercise (Stage 1): Personal Beliefs Exemption from Mandatory Immunization of Children for School Entry [see below].
2. Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years—United States, 2015, 64 MMWR 93-94 (Feb. 6, 2015) [see ASLME website].
3. CDC, Outbreak of Measles—San Diego, California, January-February 2008, 57 MMWR 1-4 (Feb. 22, 2008) (Early Release) [see ASLME website].
4. Pediatric Infectious Disease Society Statement Regarding Personal Belief Exemption from Immunization Mandates (www.pids.org/images/stories/pdf/pids-pbestatement.pdf) [see ASLME website].
Stage 2

1. Exercise (Stage 2): Personal Beliefs Exemption from Mandatory Immunization of Children for School Entry [see below].
2. Governor Edmund G. Brown, Jr., To the Members of the California State Assembly (Sept. 30, 2013) [see ASLME website].
3. California Department of Public Health, Personal Beliefs Exemption to Required Immunizations, CDPH 8262 (Oct. 2013) [see ASLME website].

Postscript

1. CDC, Measles Outbreak—California, December 2014–February 2015, 64 MMWR 153-54 (Feb. 20, 2015) & 196 (Feb. 27, 2015) [see ASLME website].
2. California Department of Public Health, California Measles Surveillance Update (April 10, 2015) [see ASLME website].
3. Senate Bill No. 277 (Approved by Governor June 30, 2015) [see ASLME website].

*These materials are not provided but can be obtained for student use in accordance with the access policies for educational use of journal articles followed by the instructor’s institution.

Reference

1. An electronic database, CAIR (California Immunization Registry), has now been established, which once completely updated and kept current should contain information on the birth and vaccination history of all children in the state; it can be accessed by schools as well as by healthcare providers, unless a parent declines to allow access.

Personal Beliefs Exemption from Mandatory Immunization of Children for School Entry

Stage 1: Analysis of the Legislative Proposal

State requirements that children entering school settings (typically, at time of entry to pre-school or childcare program, kindergarten, and seventh grade) have received all required immunizations for vaccine-preventable childhood diseases have been very effective in achieving high immunization coverage and assuring herd immunity that not only prevents disease outbreaks but protects members of the community who are unable to be vaccinated (e.g., too young; immunosuppressed; etc.). California is one of twenty states that allow parents, guardians or emancipated minors to file a Personal Beliefs Exemption (PBE) to opt out of one or more vaccines, based on their beliefs about immunization. Parents typically exercised their right to reject vaccination by simply signing a pre-written affidavit that appears on the so-called “Blue Card” (the School Immunization Record which a school must have for every enrolled child).

In California, as elsewhere across the country, a rapidly growing number of parents express hesitancy about the safety and efficacy of vaccination. Between 1996 and 2010, the rate of PBEs for children entering kindergarten rose 380%, from 0.5% to 2.3%. This increase is fed not only by popular media coverage of the views of a few celebrities and physicians who are vocal “vaccine skeptics” and who have fueled parental concern that immunization causes autism and other conditions but also by the social-group influences that produce pockets of vaccine resistance. Thus, while most of California’s counties have continued to see rising rates of PBEs (to a state-wide rate of 2.7 per 100 kindergarteners in 2012), in five counties, the rate is now over 10 per 100 kindergarteners. While such high rates are mostly found in the more remote parts of northern California, clusters are also found in urban areas; for example, in one city in Los Angeles County, 59% of students had a PBE on file at kindergarten entry.

The risk of unvaccinated children contracting diseases such as measles is up to 35-fold that of children who have been vaccinated, and clusters with high numbers of vaccine-refusers therefore pose a serious risk of outbreaks. For example, a 2008 measles outbreak in San Diego, which was linked to a child whose parents had refused vaccinations, involved a dozen children; three were too young to be vaccinated, but all but one of the others had PBEs on file. In addition to parents who are skeptical about vaccination programs, some may sign a PBE as a path of least resistance, perhaps with the encouragement of school personnel, who may feel that their main responsibility is to get children enrolled in school and who are not aware of, or sufficiently concerned about, the risk posed by growing rates of non-immunized children in their communities to undertake the trouble associated with following up with families whose children have been “conditionally” admitted, pending getting the required immunizations. (Although it might seem that particularly high rates of PBEs would therefore be found in communities with large numbers of poor, migrant families, who may lack well-established relationships with healthcare practitioners and who, with frequent moves, might have trouble keeping track of immunization records as they move their children from school to school, the areas in California where
such families are prevalent do not have particularly high rates.)

Consider the following bill in the California legislature (as amended as of August 20, 2012) as a means to address the PBE problem. It was modeled on a Washington statute requiring parents to discuss vaccination with a health practitioner before signing a PBE. The year after that law was adopted, Washington State saw a drop in PBEs from 6% to 4.5% of entering students.

**Assembly Bill No. 2109**

An act to amend Section 120365 of the Health and Safety Code, relating to communicable disease.

**LEGISLATIVE COUNSEL’S DIGEST**


Existing law prohibits the governing authority of a school or other institution from unconditionally admitting any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless prior to his or her first admission to that institution he or she has been fully immunized against various diseases, as specified.

Existing law exempts a person from the above-described immunization requirement if the parent or guardian or other specified persons file with the governing authority a letter or affidavit stating that the immunization is contrary to his or her beliefs.

This bill would instead require this letter or affidavit to document which required immunizations have been given, and which immunizations have not been given on the basis that they are contrary to his or her beliefs.

This bill would instead require this letter or affidavit to document which required immunizations have been given and which have not been given on the basis that they are contrary to the parent or guardian's or other specified person's beliefs. The bill would require, on and after January 1, 2014, the letter or affidavit to be accompanied by a form prescribed by the State Department of Public Health that includes both of the following:

1. A signed attestation from the health care practitioner that indicates that the health care practitioner provided the parent or guardian of the person, the adult who has assumed responsibility for the care and custody of the person, or the person, if an emancipated minor, who is subject to the immunization requirements with information regarding the benefits and risks of the immunization and the health risks of specified communicable diseases. The bill would require the form to include a written statement by the parent, guardian, other specified persons, or person, if an emancipated minor, that indicates that he or she received the information from the health care practitioner.

2. A written statement signed by the parent or guardian of the person who is subject to the immunization requirements of this chapter, the adult who has assumed responsibility for the care and custody of the person, or the person if an emancipated minor, with information regarding the benefits and risks of the immunization and the health risks of the communicable diseases listed in Section 120335 to the person and to the community. This attestation shall be signed not more than six months prior to the date when the person first becomes subject to the immunization requirement for which exemption is being sought.

**BILL TEXT**

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Section 120365 of the Health and Safety Code is amended to read:

120365. (a) Immunization of a person shall not be required for admission to a school or other institution listed in Section 120335 if the parent or guardian or adult who has assumed responsibility for his or her care and custody in the case of a minor, or the person seeking admission if an emancipated minor, files with the governing authority a letter or affidavit that documents which immunizations required by Section 120355 have been given, and which immunizations have not been given on the basis that they are contrary to his or her beliefs.

(b) On and after January 1, 2014, a form prescribed by the State Department of Public Health shall accompany the letter or affidavit filed pursuant to subdivision (a). The form shall include both of the following:

1. A signed attestation from the health care practitioner that indicates that the health care practitioner provided the parent or guardian of the person who is subject to the immunization requirements of this chapter, the adult who has assumed responsibility for the care and custody of the person, or the person if an emancipated minor, with information regarding the benefits and risks of the immunization and the health risks of the communicable diseases listed in Section 120335 to the person and to the community. This attestation shall be signed not more than six months prior to the date when the person first becomes subject to the immunization requirement for which exemption is being sought.

2. A written statement signed by the parent or guardian of the person who is subject to the immunization requirements of this chapter, the adult who has assumed responsibility for the care and custody of the person, or the person if an emancipated minor, that
indicates that the signer has received the information provided by the health care practitioner pursuant to paragraph (1). This statement shall be signed not more than six months prior to the date when the person first becomes subject to the immunization requirements as a condition of admittance to a school or institution pursuant to Section 120335.

(c) The following shall be accepted in lieu of the original form:
1. A photocopy of the signed form.
2. A letter signed by a health care practitioner that includes all information and attestations included on the form.

(d) Issuance and revision of the form shall be exempt from the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

(e) When there is good cause to believe that the person has been exposed to one of the communicable diseases listed in subdivision (a) of Section 120325, that person may be temporarily excluded from the school or institution until the local health officer is satisfied that the person is no longer at risk of developing the disease.

(f) For purposes of this section, “health care practitioner” means any of the following:
1. A physician and surgeon, licensed pursuant to Section 2050 of the Business and Professions Code.
2. A nurse practitioner who is authorized to furnish drugs pursuant to Section 2836.1 of the Business and Professions Code.
3. A physician assistant who is authorized to administer or provide medication pursuant to Section 3502.1 of the Business and Professions Code.
4. An osteopathic physician and surgeon, as defined in the Osteopathic Initiative Act.
5. A naturopathic doctor who is authorized to furnish or order drugs under a physician and surgeon’s supervision pursuant to Section 3640.5 of the Business and Professions Code.
6. A credentialed school nurse, as described in Section 49426 of the Education Code. SEC. 2. If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

In addition to AB 2109, read the following:

Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 Through 18 Years – United States, 2015, 64 MMWR 93-94 (Feb. 6, 2015).


Pediatric Infectious Disease Society Statement Regarding Personal Belief Exemption from Immunization Mandates (www.pids.org/images/stories/pdf/pids-pbe-statement.pdf)

Stage 1: Analysis of the Legislative Proposal
You are the member of a legal team that has been asked by one of the following groups to prepare an analysis of the bill and to recommend whether the group should support its adoption. (Some of the groups listed may be actual organizations; others are hypothetical. The basic views of each group are presented but you are free to extrapolate additional concerns or positions that would be consistent with the group’s orientation.) Anticipate and respond to objections to the positions you develop on behalf of your client.

A. The American Academy of Pediatrics
When contacting your team, the executive director of this group informed you that the Academy has long been on record favoring universal vaccination of children and has been very critical of physicians who are public “vaccine deniers.” The group recognizes that the professional advice (and signature on a form) that pediatricians may be asked to provide by families that want to file a PBE is a service that many health insurance policies may not cover. At the same time, the Academy’s board members are concerned that obtain-
ing the necessary attestation from a healthcare provider should not be significantly easier than obtaining the required vaccinations.

B. The Local Department of Public Health
The department’s director informed your team that the department has always strongly supported childhood vaccination. She noted that the official position of the National Association of County and City Health Officials (NACCHO) is that PBEs be removed from state immunization laws and regulations; pending such action, the organization urges that the availability of PBEs be limited. The department is concerned, however, about two things. First, it may face a net increase in work, not only at its Community Health Centers, where it has provided vaccinations and counseling to eligible families but also in having to provide materials to and educational programs for school personnel. Second, they believe that the information provided and attestation signed by the parents or guardians under the bill are not sufficiently direct and forceful concerning the risks in failing to obtain the recommended vaccinations. Instead of “information regarding the benefits and risks of the immunization and the health risks of the communicable diseases listed in Section 120335 to the person and to the community,” they suggest that parents should have to acknowledge that they have been informed “that without vaccination, their child is at significantly higher risk of illness, disability and death and is also placing other people with whom the child comes into contact at higher risk of illness, disability and death should the child become infected.”

C. Parents United Against Forced Vaccinations
The president of this group reports that they want to eliminate immunization as a condition for school enrollment for a number of reasons. Some of their members hold religious objections to vaccination; some are libertarians and don’t believe it is right for the government to force people to do things “for their own good” or to take risks to protect others against problems they don’t create (such as a naturally occurring disease); and some believe medical groups and government officials are lying when they insist that vaccinations are beneficial for children and do not cause autism or other developmental problems.

D. California Association of School District Superintendents
The chair of the CASDS board told your team that PBEs put school personnel in an awkward position because of the central conflict between their need to enroll students and their recognition that unvaccinated students present a risk to themselves and others. In terms of administering the revised PBE, the group points out that the persons handling school enrollment typically lack either the knowledge or the authority to respond to questions from parents about the relative risks and benefits of childhood immunization (particularly from parents who strongly object to vaccinations because of what they have read in the media); many schools lack full-time school nurses, who would be able to answer questions and provide the proposed attestation that the parents have received the required explanation of vaccination’s risks and benefits; and their schools are understaffed to pursue the immunization status of children who lack evidence of required vaccinations but who are conditionally admitted to school based upon their parents’ promise to get them vaccinated promptly. Finally, the school superintendents are concerned that parents, who will be annoyed at the added burden of having to obtain an attestation from a healthcare provider, will direct their ire at school personnel.

E. American Society for Fair and Equal Treatment
This group’s leader informs your team that its members believe that the personal beliefs exemption is actually a form of religious exemption, which treats non-believers unfairly; in effect it creates a privilege for people who adhere to particular religious beliefs. They also think that the law should make people who refuse having their children vaccinated for non-medical reasons liable for harm suffered by other children who acquire a vaccine-preventable disease from a child whose parents registered a PBE against immunization.

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Personal Beliefs Exemption from Mandatory Immunization of Children for School Entry

Stage 2: Implementing the Statute
The California Assembly approved AB 2109 on May 10, 2012. A series of amendments in the Senate produced the version you read in Stage 1, which was approved by the Senate (2214) on August 22. On August 27 the Assembly concurred in the Senate amendments (51-29). The bill was then enrolled and presented to the Governor on September 6, and upon his approval on September 30, 2012, it entered into law, as Chapter 821, Statutes of 2012.

When approving the law, however, Governor Brown sent a “signing message” to the Members of the California State Assembly (which is attached to
this assignment) in which he praised the statute on the ground that getting an explanation of “the value of vaccinations—both the benefits and risks—for an individual child and the community” will be “valuable” whether or not parents choose to vaccinate. He stated that he was directing the State Department of Public Health “to oversee this policy so parents are not overly burdened in its implementation.” Perhaps to elaborate what he meant by this, he then added: “I will direct the department to allow for a separate religious exemption on the form. In this way, people whose religious beliefs preclude vaccinations will not be required to seek a health care practitioner’s signature.”

I. What position should the group that you represented in Stage 1 take on how the Department of Public Health, local health departments, and schools should respond to the instructions in Governor Brown’s statement? Consider, for example:

A. How does Governor Brown’s directive to the California Department of Public Health differ from the instructions provided to the department in the statute?
B. What is the status of signing statements by a state or national chief executive?
C. What new legal issues has the governor potentially inserted into the exemption process?
D. What could any group do if it objected to the PBE form issued by the department in conformity with the governor’s instructions?

II. In October 2013, the public health department issued the new form for recording a “Personal Beliefs Exemption to Required Immunization,” to become effective on Jan. 1, 2014. (That form, CDPH 8262, is attached.) What position would you advise your client to take on the form?

F. How does the form differ from the instructions issued by the governor?
G. If your client has an objection to the form, should the client raise the objection or wait to see what results the form produces? If you recommend that the client object now, what steps should the client take to raise the objection or provoke litigation to challenge the form, on the ground that it does not match the statute or on some other ground? If your client supports the form, what role could it play in litigation brought by others?
H. Why do you think the statute and form will or will not reduce the rate at which PBE are exercised by parents when enrolling children in school?

Acknowledgement
Support for the Scholars in Residence fellowship program was provided by the Robert Wood Johnson Foundation.
Courses on bioethics and the law traditionally have focused their coverage on ethical issues arising from individual patients’ encounters with the medical care system, but the course also provides an excellent opportunity to expose students to ethical issues arising at the intersection of medical care and public health. The following materials were assembled for use near the end of a semester-long law school course in Bioethics & Law. I taught the course relying heavily on problems contained in Barry R. Furrow et al., Bioethics: Health Care Law and Ethics, 7th ed. (2013), which was the primary text for the course. For each Problem assigned from the casebook:

- 1-3 students were responsible for drafting a short memo (4-7 pages) addressed to their supervising attorney. The memo’s purpose was to respond to questions posed by the client seeking advice in the Problem.
- For most Problems, I also drafted “Supplementary Instructions” to focus students’ attention on particular questions of concern to their clients.
- The memo writers turned in first drafts of their memos prior to the class meeting in which the full class would discuss the Problem, and they were expected to be the experts in that discussion.
- Following the class discussion and after I provided extensive written feedback to students on both the style and substance of their draft memos, the students had a week to submit a revised memo.

By using this approach, I sought simultaneously to:

1. foster students’ understanding of the substantive legal and ethical questions presented by the Problems;
2. develop students’ ability to consider client concerns and priorities in their analysis of legal and ethical issues; and
3. provide students with meaningful feedback on multiple instances of practice-oriented writing. (Each student wrote three memos over the course of the semester.)

The Furrow Bioethics casebook includes a short chapter on ethical issues relating to public health. The public health materials come at the very end of the casebook and provide a nice opportunity to introduce the population-level concerns and social welfare goals of public health as a contrast to the individual patient-level concerns that dominate most of the Bioethics course. In particular, the materials on mandatory vaccinations and nonmedical exemptions present meaty questions that call on students to consider how to reconcile or balance issues regarding parental autonomy, child welfare, and social welfare. I supplemented the
The materials on mandatory vaccinations and nonmedical exemptions present meaty questions that call on students to consider how to reconcile or balance issues regarding parental autonomy, child welfare, and social welfare. I supplemented the casebook’s coverage by assigning students to read a series of blog posts regarding potential tort liability for parents who fail to vaccinate their children. Throwing into the mix questions about potential parental liability highlights the third-party individual interests at stake when parents make a decision not to vaccinate their child and provides the basis for a rich discussion of whether public health law and tort law complement or potentially undermine one another in terms of accomplishing social goals and how those social goals should be balanced against individual rights and concerns. A number of these questions are suggested in the “Questions for in-class discussion” that I included as part of students’ assigned reading for this class.

In addition to the following materials, students were also assigned to read Chapter 8 (“Population Health and Public Health”) of the Furrow Bioethics casebook prior to the class meeting on this topic.

**Vaccine Exemptions, Tort Liability, and Public Health**

Assigned reading:

1. Chapter 8: Population Health and Public Health (pp. 565-579), including “Problem: Exemptions from Immunization Requirements” (p. 577)
2. Supplementary instructions for “Problem: Exemptions from Immunization Requirements” [see below]
3. Supplementary reading: “Vaccine Exemptions, Herd Immunity, Public Health and Individual Responsibility – online resources” [see below]
4. Questions for in-class discussion [see below]

**Problem: Exemptions from Immunization Requirements**

You are the legal counsel to the school district in Gadsden, Alabama. The Code of Alabama, § 16-30-1, et seq., requires certain immunizations as a condition of school attendance. Exemptions to this provision are found in § 16-30-3:

The provisions of this chapter shall not apply if:

1. In the absence of an epidemic or immediate threat thereof, the parent or guardian of the child shall object thereto in writing on grounds that such immunization or testing conflicts with his religious tenets and practices; or
2. Certification by a competent medical authority providing individual exemption from the required immunization or testing is presented the admissions officer of the school.

First grader Miranda Black’s parents, who resent the heavy burden of government, have decided that they will not submit to any immunization requirement. They reason that Miranda should not have to shoulder the public health value of immunization by risking the side effects of the immunizations. Her doctor will not provide the “certification” that the school authorities want because there is no medical reason for her to avoid immunization, and thus her parents have submitted to the school authorities a statement that “compulsory immunization violates our Christian view that the government cannot make
us do anything.” School health officials are concerned because there were four cases of whooping cough in Gadsden during the last year—up from two the year before, and one the year before that. They attribute the increase to the increasing number of people who have obtained exemptions. The school officials have asked you how they should react to the request that Miranda be exempt.


Supplementary Instructions for Problem:
Exemptions from Immunization Requirements

You are an associate in the law firm that is legal counsel for the Gadsden, Alabama school district, and your boss has presented you with the facts and questions posed in the Problem. Prepare a memo for him identifying and reasoning through the legal issues raised by the exemption request by Miranda Black’s parents. You should conclude by suggesting to your boss how he should advise the school board.

In giving you this assignment, your boss also mentioned that the superintendent of schools made a comment to him that “if Miranda Black ends up getting whooping cough or some other disease and spreads it to other kids, it would serve her parents right if they got sued.” This offhand comment made your boss wonder whether parents opting out of immunizations might in fact face potential liability, and he has asked you to include in your memo your analysis of the potential liability of such parents.

Supplementary Reading:

- **Vaccine Exemptions, Herd Immunity, Public Health and Individual Responsibility – online resources**
  The CDC provides the following definition for “community immunity,” also known as “herd immunity”:

  Community immunity: A situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely. Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community. Also known as herd immunity.

  See <http://www.cdc.gov/vaccines/about/terms/glossary.htm#c>

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  For a short article and graphics on the impact on herd immunity of families forgoing vaccinations for their children, see (and please read): <http://www.scientificamerican.com/article.cfm?id=too-many-children-go-unvaccinated>

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  The commentary below was posted during May and June 2013 on the Bill of Health blog (http://blogs.law.harvard.edu/billofhealth/), published by the Petrie-Flom Center at Harvard Law School

  Liability for Failure to Vaccinate
  Posted on May 23, 2013 by acaplan
  By Art Caplan

  Measles are breaking out all over Britain. Getting fewer headlines is the fact that measles are back in the USA too. In fact they are in our region. A mini-epidemic is raging in Brooklyn. Measles for cripes sake! The disease that many of us over 60 had as kids that should never occur is back with a vengeance. The reason for the diseases reappearance is simple—failure to vaccinate. Maybe it is time to get tough on those whose choices put others at risk.

  For decades, there has been a safe, effective vaccine that works exceedingly well against the measles—95% full protection for a kid who has been vaccinated— and nearly equally well at preventing transmission to others. The more people have been vaccinated the tougher it is for measles to gain a foothold.

  NY City health officials have reported 30 cases so far—26 in Borough Park and four more in Williamsburg. The NY Daily News reports that the consequences of this outbreak have been dire: “There have been two hospitalizations, a miscarriage and a case of pneumonia as a result of this outbreak,” a Health Department spokesperson
said. “All cases involved adults or children who were not vaccinated due to refusal or delays in vaccination.”

So far the outbreak has been among religious Jews some of whom shun getting the vaccine for their kids out of fear it causes autism Dr. Yu Shia Lin of Maimonides Medical Center in Borough Park told The News.

Hasidic Jews in Brooklyn are not the only ones making poor, dangerous and sometimes fatal choices by avoiding vaccination. 20 people were sickened a few weeks ago in North Carolina when an unvaccinated person came back from India, attended two youth baseball games, and later, developed symptoms of measles having exposed many people. An infant in Battle Creek, Michigan, whose parents traveled out of the country without vaccinating their child against measles likely exposed others to measles at a pediatric office and subsequently at the emergency room where their measles-infected child was taken. And Britain is battling an enormous outbreak of measles directly attributable to non-vaccination.

Pockets of measles spring up in places where parents choose for one reason or another not to vaccinate and then take an infected child on a bus, to an airport, to daycare, an amusement park, a church or other public places.

For many years public health officials have tried to debunk false fears about vaccine safety. Public officials have tried to make vaccination a condition of entering school. But choosing not to vaccinate is still permitted. Some parents home school to duck the vaccination requirement. And some parents just won’t believe that the vaccines are safe no matter how many studies prove otherwise.

I think there should be a right to decide not to vaccinate your child. But, we have been far too lenient in putting up with the consequences of that lousy choice. If your kid gets the measles, and remember public health officials are getting very very good at tracing outbreaks to their source, and makes my kid sick (can happen since vaccine is not 100% effective), my newborn baby die (newborns can’t benefit from vaccines) or my wife miscarry (fetuses are at especially high risk), then shouldn’t I be able to sue you for the harm you have done?

Some will say that the law in NY and other states allows refusal and that protects against liability. Maybe.

If you know the dangers of measles or for that matter whooping cough or mumps, and you still choose to put others at risk should you be exempt from the consequences of that choice? I can choose to drink but if I run you over it is my responsibility. I can choose not to shovel the snow from my walk but if you fall I pay. Why should failing to vaccinate your children or yourself be any different?

When the subject is vaccines a tiny minority continue to put the rest of us at risk. We are willing to let them choose to do so without penalty. That should change. If I know you or your kid made mine sick because you chose not to vaccinate then you should bear full responsibility for the harm you knew or ought to have known could happen.

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Guest Post: Crack Down on Those Who Don’t Vaccinate?: A Response to Art Caplan
Posted on June 21, 2013 by petrieflom
By Mary Holland, J.D.

Mary Holland is Research Scholar and Director of the Graduate Legal Skills Program at NYU Law School. She has published articles on vaccine law and policy, and is the co-editor of Vaccine Epidemic: How Corporate Greed, Biased Science and Coercive Government Threaten Our Human Rights, Our Health and Our Children (Skyhorse Publishing, 2012).

Dr. Art Caplan recently posted an editorial, “Liability for Failure to Vaccinate,” on this blog. He argues that those who contract infectious disease should be able to recover damages from unvaccinated people who spread it. If you miss work, or your baby has to go to the hospital because of infectious disease, the unvaccinated person who allegedly caused the harm should pay. Dr. Caplan suggests that such liability is apt because vaccines are safe and effective. He sees no difference between this situation and slip-and-fall or car accidents due to negligence. Arguing that “a tiny minority continue to put the rest of us at risk,” he suggests that public health officials can catch the
perpetrators and hold them to account through precise disease tracing.

Dr. Caplan’s assertions to the contrary, vaccines are neither completely safe nor completely effective. In fact, from a legal standpoint, vaccines, like all prescription drugs, are “unavoidably unsafe.” [See, e.g., Bruese witz v. Wyeth, 562 U.S. ___ (2011). ] Industry considered its liability for vaccine injury so significant that it lobbied Congress for the 1986 National Childhood Vaccine Injury Act, providing doctors and vaccine manufacturers almost blanket liability protection for injuries caused by federally recommended vaccines. [See Authorizing Legislation.] The liability risk was so serious that the federal government created a special tribunal under the 1986 Act, the Vaccine Injury Compensation Program, to pay the injured. Moreover, the Supreme Court in 2011 decided Bruese witz v. Wyeth, prohibiting any individual from filing a civil suit for a defectively designed vaccine in any court in the country. Industry’s extraordinary protection against liability for vaccine injury does not correspond with glib statements, like those of Dr. Caplan, that vaccines are safe and effective. On the contrary, the law acknowledges that vaccines cause injury and death to some, with no screening in place to mitigate harm. Dr. Caplan notes that public health officials have “tried to debunk false fears about vaccine safety.” Yet the Institute of Medicine, one the country’s most prestigious health organizations, has acknowledged repeatedly that there are many known vaccine injuries, such as seizures from the measles-mumps-rubella vaccine, anaphylaxis from the meningococcal vaccine, and encephalitis from the varicella vaccine. Even more troubling than the identified injuries is the number of potential vaccine adverse effect relationships for which the evidence is not sufficient to either prove or disprove causality. [Committee to Review Adverse Effects of Vaccines, Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2012).] Dr. Caplan seems to suggest a peculiarly narrow kind of civil liability, allowing claims only by those who have been vaccinated and become sick against those who lawfully refused vaccination. What if a vaccinated person spreads disease? Presumably, she would bear no liability because she would not have been negligent. Yet vaccinated people do spread disease, as in the case of Tenuto v. Lederle Labs., 907 NYS.2d 441 (2010). Mr. Tenuto, a father, contracted paralytic polio from his infant daughter while changing her diaper after the infant had received the live virus oral polio vaccine. Although the vaccine protected the infant from polio, it exposed her father to disease through viral shedding, causing him severe, lifelong harm. Despite proven causation, industry litigated for over thirty years to avoid paying for the damages that occurred before the 1986 liability protections took effect.

And what if disease breaks out in a highly vaccinated population, with no unvaccinated person to finger? There have been numerous outbreaks of mumps, measles and pertussis with no initial cases traced to unvaccinated individuals. [See, e.g., Nkowane et al, “Measles Outbreak in a Vaccinated School Population: Epidemiology, Chains of Transmission and the Role of Vaccine Failures,” AJPH April 1987, 77, no. 4.] Presumably, Dr. Caplan would argue no liability should inure to industry because the sale of ineffective or defectively designed vaccines does not constitute negligence.

Dr. Caplan’s interest to hold liable families lawfully exercising religious freedom while letting industry have almost complete liability protection seems peculiarly asymmetrical and unjust. Overall, Dr. Caplan seems to suggest an implied duty to vaccinate on all members of society. Yet the legal foundation for such a duty is shaky, as there is no clear analogue in tort or criminal law for a duty to rescue, even if a person may do so at little or no cost to herself. [See, e.g., Ernest J. Weinrib, The Case for a Duty to Rescue, 90 Yale L.J. 247 (1980) (evaluating the case for imposing a duty to rescue).] If the common law has been unwilling to impose a duty to rescue, Dr. Caplan is likely wrong as a matter of law to suggest that civil liability is a viable work-around for limiting religious vaccination exemptions.

New York State law permits people to refuse vaccines for “genuine and sincere religious beliefs.” [N.Y. Pub. Health Law Section 2164(1)(a) (Consol.2011).] The rationale behind this is that some people have deeply held religious and ethical convictions that conflict with vaccination. Freedom of religion is the first civil right in the First Amendment to the U.S. Constitution; it is the bedrock of U.S. law and culture. Similarly, religious tolerance is a cornerstone of New York State’s historic peace and prosperity. The right to
affirm a religious objection to vaccination is part of New York's heritage. To repeal that, or to subvert it through civil liability, would be to unravel some of the bonds that hold together New York's extraordinarily diverse society.

Concerns about infectious disease outbreaks are real, however. In the event of an outbreak, unvaccinated children must remain home from school until the outbreak subsides. Such lawful quarantines during public health emergencies respect the rights of all, including the unvaccinated.

Despite sharp disagreement about civil liability, on one important point Dr. Caplan and I agree. He notes in his post that “newborns can’t benefit from vaccines.” Dr. Caplan is correct that there is no compelling science suggesting that newborns’ undeveloped immune systems can benefit from vaccination. Given this acknowledgement, I expect that Dr. Caplan agrees that the federal recommendation that newborns receive the hepatitis B vaccine while still in the hospital is unwise. Dr. Caplan appears to agree that the infant hepatitis B vaccine recommendation and its associated mandates are irrational and violate the Constitution’s 14th amendment equal protection and due process clauses. [See Mary Holland, Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children, 12 Yale J. Health Pol’y L. & Ethics 39 (2012).]

Dr. Bernadine Healy, the late Director of the National Institutes of Health, wrote, “Vaccine policy should be the subject of frank and open debate, with no tolerance for bullying. There are no sides – only people concerned for the well-being of our children.” [book cover blurb, Vaccine Epidemic.] In that spirit, I commend Dr. Caplan for initiating an important debate about civil liability, religious freedom and vaccination.

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Guest Post: No Liability for Failure to Vaccinate? The Case Has Not Been Made: A Response to Mary Holland

By Dorit Rubinstein Reiss, LLB, Ph.D.

Dorit Rubinstein Reiss (LLB, Ph.D.) is Professor of Law at UC Hastings College of the Law. She has published articles on regulation and administrative law and teaches tort law. She is also a member of the Parents Advisory Board of Voices for Vaccines and writes the blog Before Vaccines.

In a guest post on this blog, Mary Holland, JD, suggests that there are no grounds for imposing tort liability on parents for failure to vaccinate alone, even if it led to another person being infected. Holland’s post is courteous and matter-of-fact, and there are certainly arguments for that position, especially the argument that common law rarely imposes a duty to act. But Ms. Holland did not make that case.

A. Absence of a Common Law duty

Ms. Holland correctly identifies that courts are reluctant to impose a duty to act or rescue. Our legal system accords great weight to personal autonomy and therefore hesitates to require people to act. However, there are exceptions to this general approach, cases in which courts do impose a duty to act, so identifying that this is a duty-to-act situation is the start of a discussion, not the end of it. Duty is a legal determination by the court, not an objective, observable phenomenon independent of human will; “duty’ is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection,’ Dillon v. Legg, 68 Cal. 2d 728, 730 (Sup. Ct. 1968), quoting Prosser. Various courts have imposed a duty to act on a psychiatrist who knows of a threat a patient poses to others (Tarassoff v. Regents of the University of California, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976)); on a host to protect social guests from defects on the premises (Rowland v. Christian, 69 Cal. 2d 108 (1968)); on friends on a “joint venture” to render assistance when the friend is injured (Farwell v. Keaton, 396 Mich. 281, 240 N.W.2d 217 (1976)). Legislatures, too, may impose a duty to act.

There are several ways to analyze duty. Using the traditional Rowland v. Christian, 69 Cal. 2d 108 (1968) factors, we balance, among others, “the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant’s conduct and the injury suffered, the moral blame attached to the defendant’s conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences
to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved.” Out of all these factors, Holland’s analysis focused solely on the burden to the defendant, ignoring all the other considerations. Holland’s arguments that the duty creates too high a burden are that the duty violates religious freedom — addressed in part B — and that vaccines are unsafe. To show vaccines are unsafe Holland refers to Bruesewitz v. Wyeth, 562 U.S. __ (2011), saying the court found vaccines “unavoidably unsafe”; note, however, the majority in that case actually rejected the application of that term to vaccine injuries: “... there is no reason to believe that §300aa–22(b)(1) was invoking it. The comment creates a special category of ‘unavoidably unsafe products,’ while the statute refers to ‘side effects that were unavoidable.’” That the latter uses the adjective “unavoidable” and the former the adverb “unavoidably” does not establish that Congress had comment k (where the “unavoidably unsafe” language originates) in mind. “Unavoidable” is hardly a rarely used word. Nowhere does the majority say or suggest that vaccines carry a particularly high level of risk. The Court actually speaks positively of vaccines’ contribution to public health and sees them as “victims of their own success.”

Holland uses the National Vaccine Injury Compensation Program (NVICP) as evidence vaccines are unsafe; if that is our measure of vaccine safety, vaccines are extremely safe. In the 24 years of its operation, since 1989, the program awarded compensation for slightly less than 3300 cases. As calculated elsewhere, this is less than 0.003% of the vaccine administered. The fatalities - not injuries – from motor vehicle accidents (35,900) and accidents around the home (65,200) were much more numerous in 2009 alone. Children are safer being vaccinated than driven in a car or being home. And Holland completely ignores the benefits from vaccinating, i.e. protection of the defendant’s own children against preventable diseases. Like driving or being at home, vaccines are not completely risk free. But serious harms from vaccines are rare and they provide benefits to the person vaccinated.

There is an argument that imposing such a duty constitutes a burden on the defendant; however, it was not well supported here. An argument emphasizing personal autonomy and a forcing the defendants to subject their children to something they believe is dangerous would be stronger. The defendant’s autonomy and the defendant’s parental rights are both certainly being infringed here. I see the other factors as stronger than this infringement, but the torts system rejected duty to act even in cases where the infringement of autonomy was slight.

Addressing the other factors, the harm is probably foreseeable, since we know of cases where unvaccinated individuals spread disease to others (see also “Medical Care for Unvaccinated Children”), its extent can be severe, and the results to the community from imposing liability, whether the result would be that more people vaccinate and hence less outbreaks would occur or that there will be coverage of the plaintiff’s health costs, are positive. To me, this would suggest a pretty strong case for creating such a duty, that, to counter, needs powerful arguments in response.

Note also that this is no barrier against a claim based on negligent action; for example, that non-vaccinating parents actively exposed someone else’s newborn to an unvaccinated child or intentionally exposed an unvaccinated child to a disease such as chicken pox and then let that child expose others.

Of course, even if we find a duty, a plaintiff will still have to show the other elements of negligence; the arguments about vaccine safety can be raised, for example, to show breach, but why use them to completely bar this entire category of claims at the duty stage?

B. Freedom of Religion and tort liability

Holland suggests that the value of religious freedom in our system prevents holding parents liable if their opposition to vaccine is based on religious grounds. But the Supreme Court upheld the application of generally applicable criminal laws to religious minorities (Emp’t Div., Dep’t of Human Res. of Or. v. Smith, 494 U.S. 872, 874 (1990), for example) and there is no reason to believe that one’s religious beliefs protect one from liability if actions taken under these beliefs harm other. Religious freedom is not the freedom to harm others.

Constitutionally too, in the context of vaccines, the last pronouncement we have from the Supreme Court is that states may require vacci-
nation on religious grounds even if this violates parental autonomy (Prince v. Massachusetts, 321 U.S. 158 (1944)). A state that chooses to offer a religious exemption is making a policy choice that it is free to rescind, since freedom of religion is not absolute. If the exemption can be rescinded in total, you cannot assume it is a complete barrier to tort liability.

Finally, the religion argument is in many cases suspect. There are small religious communities that sincerely oppose vaccination on religious grounds (and pay the price, as the orthodox community in New York recently did with an outbreak of measles, and as communities in the Netherlands paid with a rubella epidemic that led to two fetal deaths and 14 congenital infections and a measles outbreak, directly demonstrating the tension between parental religious freedom and the protection against disease of the child). Directly demonstrating the tension between parental religious freedom and protecting the child against harm. There are no doubt individuals with sincere religious concerns as well, but I would like to see some evidence of how widespread that is, since research into reasons for not vaccinating emphasizes instead safety concerns and mistrust of government and doctors, not religion (e.g., "Vaccine Criticism on the World Wide Web") – the same arguments Holland emphasized (see also, “School Vaccination Lawsuit”). Pockets of opposition aside, none of the major religions actually oppose vaccination (even the Vatican, while expressing concern about the use of cell lines to grow certain viruses used in vaccines, supports use of vaccines and even warns parents who do not vaccinate that they would be responsible before God if their child infects a pregnant mother with rubella and her fetus is harmed (see http://www.immunize.org/concerns/vaticandocument.htm, footnote 15).

C. Is it unfair to impose liability on parents who do not vaccinate while parents of vaccine-injured child cannot sue the manufacturer directly?

The focus of tort law is not retribution. A major goal is to make the victim whole. In this case, children who suffered a serious reaction to a vaccine can get compensation through the National Vaccine Injury Compensation Program. The NVICP is a reasonably plaintiff-friendly system, compared to a regular product liability suit: it applies a clear no-fault standard to design defects; for table injuries, plaintiff does not need to show causation; and it provides lawyer fees even if you lose, and an appeal to the federal courts. What is the mechanism to compensate parents whose child was infected by to an unvaccinated child? Why should they have to pay for the harm caused by a problematic choice by another family? Or would Holland suggest a no-fault mechanism there too, funded by a tax imposed on all families who do not vaccinate for reasons other than medical?

Holland also compares compensation here to the lack of compensation for outbreaks among vaccinated populations; but the torts system does not compensate every harm that happens in the world: it compensates harm caused by actors, usually with fault. If an accident happens because brakes fail, it will matter whether the brakes failed without anyone being at fault and without being defective – no liability – or if the brakes were defective (in which case you can sue the manufacturer) or the driver did not maintain them well (in which case you can sue the driver). An outbreak in a vaccinated population is not a matter of choice and fault. An infant infected with measles or whooping cough because another family chose not to vaccinate their child is another matter entirely.

Non-Medical Exemptions: Weighing Public Health and Individual Rights

More and more frequently, the media are reporting two potentially related and troubling developments: an alarming increase in outbreaks of deadly infectious vaccine-targeted diseases and the growing refusal by parents to allow their children to be vaccinated. (See this recent U.S. News & World Report article on cases in New York). Public health officials may therefore fairly ask whether their state vaccine exemption laws are unnecessarily and unintentionally sowing the seeds for a public health crisis and, if so, how their laws could be changed soon to head off avoidable epidemics.

Public health laws seek to balance the wellbeing and safety of the entire population against indi-
individual rights of self-determination, informed consent and the right to refuse medical treatments that carry the risk of injury and death. Laws mandating vaccination demand that each of us take risks to protect the community at large. Public health officials reason that vaccination of a sufficient proportion of the population creates “herd immunity” – a collective benefit derived from vaccination of the majority of the population that imparts protection to those who remain unvaccinated by impeding disease contagion.

Whether motivated by sound and well-reasoned calculation or misplaced conviction, some parents choose to shield their children from the risks associated with vaccination, yet they benefit from the protection against deadly disease that widespread vaccination confers to the community at large. If sufficient numbers of children are not vaccinated, however, both the unvaccinated children and the rest of the community become vulnerable to disease. It is at this juncture that states have the authority and a compelling interest in the health and welfare of its citizens. But what course of action is best?

Without a clear understanding of the relationship between the use of non-medical exemptions (NMEs), vaccine uptake and health outcomes, policymakers are in a difficult position. It appears that concerns about overuse of NMEs and communicable disease outbreaks have stimulated some states to restructure state NME statutes and make access to NMEs more restrictive. Below are examples of strategies two states have used to try to decrease what decision-makers believe to be inappropriate NME use.

First, in 2002 Arkansas eliminated a provision confining religious exemptions to those belonging to a specific “recognized” religion after that limitation was challenged. A new statute that went into effect in 2004 requires citizens to provide notarized requests, take a class, and sign a refusal-to-vaccinate form.

Second, New York faced the same challenge and eliminated the “recognized” religion requirement in 1989. In contrast to Arkansas’s overhaul of its exemption process, New York school administrators were tasked with examining the sincerity of the religious beliefs for some seeking an exemption. Not surprisingly, this proved controversial. One such examination was recorded and made available to the public on the Internet. The public uproar ultimately resulted in a New York Assemblywoman introducing a personal-belief-exemption bill because she thought that parents should not have “the burden of proving a religious or medical reason to refuse vaccines.”

These examples demonstrate how two states dealt in different ways with the same issue. Neither state knew whether changes in the statute or administrative regulations were likely to affect decisions to use a recommended vaccine or rates of vaccine-targeted diseases. And whether changes in the restrictiveness of these statutes affected those rates is unknown. Clearly, policymakers need such information in order to structure state vaccine exemption laws in ways that maximize health without unnecessarily restricting personal healthcare decision-making.

Appropriately reflecting the examples above, Professor Ross Silverman argues in an article published in the Annals of Health Law that, “the goal [of vaccine exemption statutes] should not be to eliminate the ability of those seeking exemption to receive relief under the law, since such an approach would exacerbate feelings of animosity and skepticism toward vaccination and the public health system in general.” Rather, the goal of state public health policymakers should be to create efficient and effective health care systems that are responsive to the needs of all its citizens.

Dr. Yang is a grantee of the Robert Wood Johnson Foundation’s Public Health Law Research program. A manuscript by Dr. Yang and colleagues detailing the effect of non-medical exemption law and vaccine uptake on vaccine-targeted disease rates has been accepted for publication at the American Journal of Public Health.

Questions for In-Class Discussion:

Contrasting Bioethics and Public Health Concerns

1. What is the nature of the individual interests at stake in the Problem and what ethical principles do they implicate?
2. How might the interests of individual citizens be pitted against one another in the context of mandatory vaccination laws?

3. Does the family physician from whom Miranda Black’s parents seek a “medical certification” have any ethical obligation to issue such a certification, simply as a matter of respecting the parents’ autonomy? Why or why not?

4. How do individual interests weigh against public health and social welfare goals in the context of laws requiring immunization as a condition of school enrollment?

5. How is the state’s interest in mandating vaccination different from the state’s asserted interest in compelling medical treatment in cases involving the refusal of medical treatment for/by children?

6. How is the phenomenon of “herd immunity” relevant to these questions? How does the fact that some individuals with medical conditions and infants cannot themselves receive vaccinations fit into the picture?

Applying the Exemption: Legal and Practical Questions

7. Can the school district assert that the recent increase in the number of whooping cough cases constitutes an epidemic, so that no exemptions are permitted? Who decides whether “an epidemic or immediate threat thereof” exists? Is that a legal issue? Or is it a medical question that requires the expert opinion of an epidemiologist or other scientific expert?

8. Should the school district question Miranda’s parents about the nature of their beliefs and compare those beliefs to established religious doctrine? Would granting exemptions based on mainstream religious beliefs, but not parents’ deeply held convictions that are not aligned with religious beliefs (so-called “philosophical exemptions”) constitute an unconstitutional establishment of religion? On the other hand, would granting an exemption based on the ground articulated by the Blacks effectively eviscerate the immunization requirement?

9. Should the fear of a conspiracy (by the government and the big pharmaceutical companies that manufacture vaccines to profit off of compulsory vaccinations that are not 100% risk free) be deemed a legally sufficient basis for opting out of the immunization program?

10. If the school district refuses to accept the parents’ claim to a religious exemption and the parents in turn sue the school district, the lawsuit is likely to receive media attention and generate a public reaction. How might the public react if the school district loses that lawsuit? If it wins? How should the school district weigh the risks of the possible public reactions in deciding how to proceed?

Thinking through Potential Tort Liability

11. As a matter of tort law, how strong are the arguments that parents who choose not to vaccinate their children may potentially be held liable to others who are infected and become ill as a result of exposure to the parents’ unvaccinated children? Along the same lines, should physicians who fail to advise parents regarding the need for vaccination, or who passively accept parents’ decisions not to vaccinate, face potential tort liability? For a discussion of these questions, see Amanda Z. Naprawa and Dorit R. Reiss, “Medical Advice and Vaccinating: What Liability?” available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2495971>.

12. Would recognizing such potential liability support or complement the goals of public health law? Are there ways in which recognition of tort liability might potentially undermine those goals?

13. Instead of potentially imposing tort liability on parents who fail to vaccinate their children, should the state impose some kind of “duty to warn” on schools or day care facilities to disclose to how many vaccine-exempt children they have enrolled? This warning would in theory permit parents whose children cannot be vaccinated for medical reasons to avoid enrolling their children in institutions with high vaccine exemptions. See Katherine Shaw Makielski, “May Contain Unvaccinated Children: Imposing a Duty to Warn in the Context of Nonmedical Childhood Vaccine Exemptions,” available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2424396>.
Possible Reforms to the Exemptions Scheme

14. Is tightening the substantive bases for exemptions (e.g., strictly limiting religious exemptions and eliminating any “philosophical exemption”) the best way for a state to minimize the number of exemptions granted?

15. How might a state revise the procedural requirements for obtaining an exemption in a way that minimizes the number of exemptions granted and simultaneously advances other public health goals? Some evidence suggests that, in states where procedures for claiming an exemption are minimal, some parents seeking exemptions are motivated not by philosophical objections, but by convenience, finding it easier to seek an exemption than to have their child immunized (the so-called “exemptions of convenience”). Or might the state impose a tax on parents who forgo vaccination without a medical reason?


16. Might there be a way to incorporate education regarding the benefits of immunization into statutory process requirements? (“The Oregon legislature, for example, recently passed a bill requiring that parents demonstrate that they have consulted a physician or watched an online educational video about the risks and benefits of vaccination before sending their unvaccinated children to school. Vermont passed a similar law in 2012, and Washington state passed one in 2011. As with eliminating philosophical exemptions, making exemption procedures more rigorous would not deter those with deeply held convictions against vaccination.” See “The Effect of Childhood Vaccine Exemptions on Disease Outbreaks,” available at <http://www.americanprogress.org/issues/health-care/report/2013/11/14/76471/the-effect-of-childhood-vaccine-exemptions-on-disease-outbreaks/>.

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I. Background
In law school we often focus on the importance of carefully crafting statutory and regulatory language. Textual ambiguities or sloppiness can significantly impair the efficacy of laws and regulations. Just as important as meticulous drafting, however, is the government’s ability to enforce its rules. In the absence of adequate enforcement resources, the government’s regulatory initiatives may well fail. The ability to promote public welfare depends as much on regulatory compliance as it does on the text of the regulations themselves.

This exercise is designed to focus students’ attention on the challenges of regulatory enforcement. It can be used in any public health law course that includes the study of regulations.

The case example is drawn from Oregon’s regulation of in-home care agencies (IHCA). IHCA employees provide clients with a variety of services, such as assistance with activities of daily living, companionship, and medication reminders, but they do not furnish skilled nursing services.

Oregon has detailed and extensive statutes and regulations governing IHCA. Oregon law provides for all of the following:

- Licensure requirements for IHCA;
- On-site inspections by state officials every three years after initial licensure, which consist of interviews and inspection of documents, including client files, personnel records, quality improvement plans, policies, and procedures;
- Employee background checks that must be conducted every three years and specific offenses that disqualify individuals;
- Caregiver qualifications and training;
- Client service plans and monitoring visits by IHCA administrators;
- Complaint filing procedures and authority to investigate complaints;
- Formal and informal enforcement actions for various violations; and
- Civil penalties.1

The content of the state’s regulations, therefore, is quite strong. Yet, Oregon is disappointed with the outcome of its efforts to regulate IHCA. Inspections generally reveal multiple violations, and many IHCA are repeat offenders. Some do not provide caregivers with adequate training, do not prepare accurate client service plans, do not conduct monitoring visits in clients’ homes, do not have proper policies and procedures, and are careless in their record-keeping. Such failures are serious because IHCA serve vulnerable elderly and disabled clients who often cannot advocate for themselves when they receive unsatisfactory care and who may even be vulnerable to abuse.

At the root of the problem is a lack of resources. Oregon has only 2.5 full-time employees dedicated to IHCA enforcement activities, and there are 130 IHCA. Approximately 30 of these are small opera-
The case example is drawn from Oregon’s regulation of in-home care agencies (IHCA). IHCA employees provide clients with a variety of services, such as assistance with activities of daily living, companionship, and medication reminders, but they do not furnish skilled nursing services.

III. Potential Recommendations
The following are the recommendations that I formulated for the Oregon Health Authority during my fellowship. The students thought of many of these on their own during the exercise. Instructors can discuss suggestions that were not identified by the students at the close of the session if they wish to address the topic more thoroughly.

Facilitating Compliance
1. Ensure that websites are easy to find. Many government agencies use websites to convey considerable information to the public, including forms and instructions relating to regulatory compliance. Some websites, however, are difficult to locate among the myriad pages run by large agencies. The government’s information technology specialists should ensure that this is not the case for high-use webpages. For example, a Google search that is intuitive, such as “Oregon Health Authority in-home care” should take the user to the correct page. Furthermore, the web address should be well known to those subject to regulation and should be included on all forms and correspondence issued by the government agency.

2. Provide extensive resource materials on the website. Agency websites should include documents that facilitate regulatory compliance. Resources that explain regulations, offer compliance checklists, and provide forms that are clear and not unnecessarily cumbersome are helpful. Thus, for example, websites should include frequently-asked-questions documents and interpretive guidance. Many agencies benefit from the work of student interns from local law schools and public health
schools, and such interns could be assigned to assist in developing these materials.

If the public can submit complaints to the agency, complaint forms with clear instructions should also be easily accessible on the website. Complaints can serve as a form of private monitoring and facilitate the agency’s oversight work.

3. Utilize listservs. Government agencies can utilize listservs to educate and inform the public. Through listservs, agencies can proactively notify regulated entities of new interpretive guidelines and materials that have been added to the website or of changes in policies and procedures.

4. Draft documents required for public distribution. Regulated entities are often required to distribute documents, such as patient rights sheets, to clients or customers. These documents provide important information to the public and should be carefully drafted. Consequently, the drafting should be done by the government agency rather than left to the discretion of regulated entities. If the agency provides the required language, it can ensure that the documents are clear, complete, and consistent among regulated entities. Documents that must be routinely distributed by regulated entities should also be readily accessible on the agency’s website.

5. Conduct quarterly phone conferences for regulated entities. It is useful for agency officials to furnish opportunities for those subject to regulation to ask them questions and open a dialogue about regulatory challenges. Quarterly phone conferences or webinars can build trust and cooperation between regulators and regulated entities and convey the sense that the government is here to serve rather than to punish. A designated government official can open the event by discussing the deficiencies that have been most frequently detected during the last quarter. This discussion should be followed by a substantial question and answer period. Summaries of quarterly calls should be posted on the agency’s website.

Regulated entities often express frustration, asserting that they find that regulations are difficult to interpret, the government is slow to respond to queries, and different officials provide variable and inconsistent guidance. Quarterly phone calls that are open to all regulated entities could go far to allay concerns and remove confusion.

6. Conduct focus groups to obtain input. Agencies can also conduct periodic focus groups with regulated entities to solicit ideas as to how compliance can be facilitated and improved. Efforts to reach out to regulated entities through phone conferences and focus groups are likely to be received enthusiastically and to generate useful input. A key to their success, however, is responsiveness. Agencies should be willing to implement changes in rules and policies if regulated entities’ complaints and suggestions have merit.

7. Provide appropriate training to enforcement personnel, including public relations training. Many public health agencies’ oversight activities include inspections and frequent contact with regulated entities. It is obvious that agencies should provide thorough substantive training to their enforcement personnel so that they are experts concerning regulatory requirements. Equally important, however, is training in the area of public relations. Maintaining a courteous and positive tone when communicating with regulated entities is a cost-free and effective tool for improving cooperation.

To this end, enforcement personnel can emphasize that they share a mission with regulated entities: providing the highest quality services to the public. Along with discussing deficiencies after inspections, surveyors should compliment regulated entities concerning things they do well. To the extent possible, agencies should cultivate a sense of partnership with regulated agencies that is devoid of resentment and hostility, while at the same time maintaining rigorous oversight and commanding respect.

8. Reexamine survey and inspection processes. Administrative agencies that conduct surveys or inspections of regulated entities should evaluate their procedures and determine whether they can be improved. Modifications should be designed to save enforcement personnel time so that they can engage in follow-up activities that verify compliance and impose penalties where appropriate. An added advantage is that modifications may reduce the burden on regulated entities and thus foster their good will.

a. Streamline inspections. Inspections should focus initially on matters that are safety-critical for the public and need not routinely check for all possible regulatory
deficiencies. Regulated entities that are in compliance in high-priority areas could be deemed to pass the inspection without further scrutiny. Those found to have serious violations upon initial examination or those against whom complaints have been filed by members of the public should be subject to more thorough inspection.

b. **Involve staff members of regulated entity.** A knowledgeable entity staff member should be asked to remain with the surveyor throughout the day and assist in reviewing files. Staff members can locate documents within files much more quickly than surveyors who are unfamiliar with the record-keeping system. They can also answer questions immediately and look up material that is stored electronically. Such assistance will expedite surveys and increase their accuracy. It will also prevent regulated entities from being cited for lacking documents that actually exist but have an atypical format or are not stored in the particular folder being reviewed.

c. **Include on-site observation.** Document review alone may be insufficient to determine whether regulated entities are fulfilling their responsibilities, especially when they are serving vulnerable populations. Consequently, on-site observation and brief client interviews can be a particularly illuminating component of inspections. Although onsite observations may be somewhat time consuming, they should not be impossible to add if surveys are streamlined, as described above. Furthermore, regulated entities may welcome the opportunity to have surveyors interact with their clients and hear first-hand that their clients are happy and satisfied. Some agencies have already found observation to be an effective oversight tool. For example, the Centers for Medicare and Medicaid Services (CMS) includes home visits in its home health agency surveys.7

**Deterring Misconduct**

9. **Implement strategic enforcement.** In the absence of robust enforcement resources, agencies should adopt a strategic enforcement approach.8 Under this model, regulators pursue the most egregious, high-end violators first (e.g., repeat offenders or those causing provable, significant harm). If penalties that are imposed on these extreme violators are adequately publicized, they should deter similarly severe misconduct.9 Once the worst violations are eliminated, the government can pursue those at the next level of severity, penalize offenders, and once again deter similar wrongdoing. The goal is to eliminate acute misconduct and slowly narrow the spectrum of violations so that they generally become less serious.

10. **Use settlement agreements to minimize administrative burdens of penalty program.** It is undeniable that imposing penalties on regulated entities generates work for regulators. Penalized parties will generally have due process rights, including discovery and hearings. However, the administrative burdens imposed by penalty programs can be minimized through a simple technique: settlement agreements. Agencies can offer violators significant penalty reductions if they waive their hearing rights. Precedent for this practice has been set by CMS, which offers home health agencies a 35% penalty decrease in return for waivers of formal hearings.10 Composing settlement agreements should not be labor-intensive because these can follow a boilerplate format after initial approval by the agency’s general counsel’s office. At its discretion, the agency may decide in particular instances to impose fines without offering settlement agreements, such as in cases involving egregious violations or repeat offenders.

11. **Post inspection reports, penalties, and correction plans on agency website.** Public disclosures of violations and penalties, including settlement agreements, may constitute a particularly effective form of deterrence.11 A 2013 study of publicly reported quality-of-care measures found that “large group practices will engage in quality improvement efforts in response to public reporting, especially when comparative performance is displayed.”12 The same will likely be true for many regulated entities.

Survey reports along with regulated entities’ plans for correction should be posted on the agency’s website. Here too CMS has set a precedent for the practice and enables users to search for assessments of home health agencies on its websites.13 Likewise, New York posts detailed quality, inspection, and enforcement information regarding its home health agencies.14 Reports concerning regu-
lated entities are often already considered public documents, but they must be specifically requested by interested parties. Posting them automatically will save agency employees time and effort because they will not need to respond to and process requests.

Regulated entities are unlikely to greet a public disclosure policy enthusiastically. If inspections occur only once every few years, entities may be very concerned about having critical reports posted as the most current information for long periods of time. A bad report may long outlive the deficiencies noted if the regulated entity quickly corrects the problems at issue. Also, citations written in technical, regulatory language may look severe to inexpert readers even though regulators recognize that they are common and relatively benign problems.

These concerns are all valid and merit serious consideration. They can be addressed in several ways. First, plans for correction should be posted along with survey reports. The text of these plans can, if appropriate, rebut objectionable deficiency findings and reassure the public that immediate and effective corrective measures will be implemented for any shortcomings that do exist. Furthermore, comparative information can put reports in perspective, allowing readers to assess each regulated entity's performance compared to that of its competitors. For example, CMS provides home health care data in three columns: the home health provider's score in various categories, the average score in the relevant state, and the national average. Finally, administrative agencies can offer informal dispute resolution mechanisms that enable regulated entities to appeal citations and have them removed from reports if their objections are meritorious.

IV. Conclusion
I was very pleased with the exercise’s outcome. The exercise supplied students with an opportunity to read and think about a comprehensive set of state regulations. The students were thoughtful and creative in formulating solutions to the problem I posed and seemed to enjoy the challenge. Most students wanted to focus on punitive deterrence measures, but with a bit of encouragement, they also suggested useful ways to support IHCAs so that they could better understand the regulations and voluntarily comply with them.

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I hope that students left the class understanding that government officials and policymakers must think as much about enforcement capacity as they do about drafting the language of the law. The very fact that regulations exist may deter some entities from engaging in misconduct regardless of how difficult compliance is or the degree to which the regulations are enforced. However, if most find compliance very burdensome and realize that violations lead to no penalties or other serious consequences, then the state’s regulatory efforts may well be largely ineffectual.

APPENDIX A
“In-Home Care Agencies” Overview

• Statute & Administrative Rules
  • ORS 443.305 to 443.355
  • OAR 333-356-0000 to 333-356-0125

• Definitions (ORS 443.305 & OAR 333-536-0005)
  • “In-home care agency” means “an agency primarily engaged in providing in-home care services for compensation to an individual in that individual’s place of residence.” It does not include a home health agency as defined under ORS 443.005.
“In-home care services” means “personal care services furnished by an in-home care agency or an individual under an arrangement or contract with an in-home care agency, that are necessary to assist an individual in meeting the individual’s daily needs, but does not include curative or rehabilitative services.”

- **Applicability** (ORS 443.095 & OAR 333-536-0010)
  - “No provision of ORS 443.005 to 443.105 [“in-home care agencies”] shall be construed to prevent repair or domestic services by any person.” ORS 443.095
  - ORS 443.305 through 443.355 does not apply to independent individuals, volunteers, family, neighbors, or to agencies offering only housekeeping or on-call staffing for facilities, or to support services provided or funded by the Department of Human Services. OAR 333-536-0010
  - Referral and matching services must not be licensed unless they: schedule caregivers, assign work, assign compensation rates, define working conditions, negotiate for a caregiver or client for the provision of services or place a caregiver with a client. OAR 333-536-0010

- **License requirements; application and fees** (ORS 443.315 & OAR 333-536-0021)
  - A license from the Oregon Health Authority is required.
  - Renewable annually.
  - Non-transferrable.
  - Change of ownership requires additional fees.
  - License must be conspicuously posted in an office that is viewable by the public (OAR 333-536-0021)

- **On-site inspection/surveys** (ORS 443.315 & OAR 333-536-0041)
  - The Oregon Health Authority must conduct an on-site inspection:
    - Prior to services being rendered; and
    - Once every 3 years thereafter
  - In lieu of on-site inspection, certification or accreditation certification may be accepted from a federal agency or approved authority (with conditions – see ORS 443.315(8))
  - An agency must permit Division staff access to any location from which it is operating its agency or providing services during survey. OAR 333-536-0041
  - All requested documents and records must be made available to the surveyor for review and copying. OAR 333-536-0041
  - A survey may include but is not limited to:
    - Interviews of clients, client family members, agency staff management and staff;
    - On-site observations of clients and staff performance;
    - Review of documents and records;
    - Client audits.” OAR 333-536-0041
  - Owner, administrator or designee is given reasonable opportunity to submit additional facts or other information to the surveyor. See OAR 333-536-0041(6)-(7)
  - If deficiencies are found during the survey, the Division shall take informal or formal enforcement action. See OAR 333-536-0041 (10)

- **Classification** (OAR 333-536-0007)
  - Classifications
    - Limited — medication reminding only
    - Basic — medication reminding and medication assistance only
    - Intermediate – medication reminding, medication assistance, and medication administration only
    - Comprehensive — medication reminding, medication assistance, medication administration, and nursing services.
  - Medication services training for caregivers must be provided by a qualified individual or entity.
  - The agency may only provide services licensed to perform based upon classification.
  - The agency may not communicate (advertise, publicity, etc…) any services other than what it is licensed to perform.

- **Services provided** (OAR 333-536-0045)
  - The services must include “the safe provision of or assistance with, personal care tasks related to one or more of the following: bathing; personal grooming and hygiene; dressing; toileting and elimination; mobility and movement; nutrition/hydration and feeding; and medication reminding.”
  - In addition to personal care tasks, an agency may provide the following upon approval of the Division: non-injectable medica-
tion assistance; non-injectable medication administration; or nursing services.

• An agency may also provide housekeeping and supportive services, including but not limited to: housekeeping; laundry; shopping and errands; transportation; and arranging for medical appointments. If the client receives housekeeping and supportive services, the agency is not required to comply with all OAR provisions for those specific clients.

• Medication reminding may be provided if the client can self-direct (see OAR 333-536-005 & 333-536-0045 for conditions). The agency must evaluate whether a client can self-direct at a minimum of every 90 days. If the client can no longer self-direct, the client must be referred to an agency with the appropriate classification.

• Organization, administration, and personnel (OAR 333-536-0050)

  - An agency owner or designee shall assume full legal, financial, and overall responsibility for the agency’s operation and serve as, or employ, a qualified administrator.

  - A qualified administrator must possess a high school diploma or equivalent; and have at least two years professional or management experience in a health-related field or program or have completed a training program approved by the Division.

  - An administrator or designee shall be responsible for the following, including but not limited to:
    - ensuring safe and appropriate services in accordance with written service plans;
    - ensuring that all personnel meet the qualification, orientation, competency, training, and education requirements in the rules;
    - ensuring that personnel assignments are consistent with the caregiver’s abilities, skills, and competence;
    - ensuring the timely internal investigation of complaints, grievances, accidents, incidents, medication or treatment errors, and allegations of abuse or neglect; and
    - ensuring timely reporting of allegations of abuse to the appropriate authority.

• Background checks; restrictions on employees convicted of certain crimes or records of substantiated abuse (ORS 443.004 & OAR 333-536-0010; 333-536-0093)

  - “An in-home care agency shall conduct a criminal background check before hiring or contracting with an individual and before allowing an individual to volunteer or provide services on behalf of the in-home care agency, if the individual will have direct contact with a client of the in-home care agency.” (ORS 443.004(2)(b))

  - If an individual has been convicted of any of the following crimes listed above, the home health agency may not employ the individual. (ORS 443.004(4))

    - Aggravated murder
    - Murder
    - Manslaughter in the first degree
    - Manslaughter in the second degree
    - Criminal negligence homicide
    - Aggravated vehicular homicide
    - Assault in the third degree
    - Assault in the second degree
    - Assault in the first degree
    - Strangulation
    - Criminal mistreatment in the second degree
    - Criminal mistreatment in the first degree
    - Kidnapping in the second degree
    - Kidnapping in the first degree
    - Subjecting a person to involuntary servitude in the second degree
    - Subjecting a person to involuntary servitude in the first degree
    - Trafficking in persons
    - Coercion
    - Public indecency
    - Private indecency
    - Child abandonment
    - Buying or selling a person under 18 year of age
    - Child neglect in the first degree
    - Possession of materials depicting sexually explicit conduct of a child in the second degree
    - Invasion of personal privacy
    - Theft in the first degree
    - Aggravated theft in the first degree
    - Organized retail theft
Theft of services if the aggregate total value of services that are the subject of the theft is $1,000 or more (Class C)

Theft of services if the aggregate total value of services that are the subject of the theft is $10,000 or more (Class B)

Burglary in second degree

Burglary in the first degree

Arson in the first degree

Computer crime (see ORS 164.377 (2) or (3))

Robbery in the second degree

Robbery in the first degree

Forgery in the first degree

Criminal possession of a forged instrument in the first degree

Criminal possession of a forgery device

Identity theft

Aggravated identity theft

Promoting prostitution

Compelling prostitution

Luring a minor

Animal abuse in the first degree

Aggravated animal abuse in the first degree

Sex crime (see ORS 181.594)

Delivery or manufacture of a controlled substance in the last 10 years

Of an attempt, conspiracy or solicitation of a crime listed above

Of a crime in another jurisdiction substantially similar to a crime listed above

If the Department of Human Services or Oregon Health Authority has "a record of substantiated abuse committed by an employee or potential employee of a home health agency, in-home care agency, adult foster home or residential facility, regardless of whether criminal charges were filed, the department or authority shall notify, in writing, the employer and the employee or potential employee." (ORS 443.004(7))

If an owner or administrator has direct contact with a client, the owner or administrator must submit background information to the Public Health Division of the Oregon Health Authority. OAR 333-536-0010

For crimes other than those identified in ORS 443.004(3), the agency must perform a weighing test (see OAR 333-536-0093 for weighing test factors).

The background check must be nationwide. OAR 333-536-0093

The agency must perform and document a query with the National Practitioner Data Bank (NPDB) and the List of Excluded Individuals and Entities (LEIE). OAR 333-536-0093

Caregiver qualifications and requirements (OAR 333-536-0070)

Caregivers must be at least 18 and have sufficient communication and language skills to enable them to perform their duties and interact with clients and other agency staff.

Caregivers must complete agency specific orientation, conducted by the agency administrator or designee prior to providing services to clients. The orientation must include:
- Caregivers’ duties and responsibilities;
- Clients’ rights;
- Ethics, including confidentiality of client information;
- The agency’s infection control policies;
- A description of the services provided by the agency;
- Assignment and supervision of services;
- Documentation of client needs and services provided;
- The agency’s policies related to medical and non-medical emergency response;
- The role of, and coordination with, other community service providers;
- Information about what constitutes medication reminding and its specific limitations; and
- Other appropriate subject matter based upon the needs of the special populations served by the agency.

Caregivers must complete appropriate training and have their competency evaluated and documented by the administrator or designee before independently providing services. Applicable training, includes:
- Caregivers’ duties and responsibilities;
- Recognizing and responding to medical emergencies;
- Dealing with adverse behaviors;
- Nutrition and hydration, including special diets and meal preparation and service;
- Appropriate and safe techniques in personal care tasks;
- Methods and techniques to prevent skin breakdown, contractures, and falls;
- Hand washing and infection control;
- Body mechanics;
- Maintenance of a clean and safe environment;
- Fire safety and non-medical emergency procedures;
- Medication reminding or administration; and
- Basic non-injectable medication services.

- Caregivers with proof of current Oregon health-care related licensure or certificate are exempt from in-home caregiver training.
- Caregivers must receive a minimum of six hours of education related to caregiver duties annually. One hour of medication administration training must be required annually if the caregiver provides medication administration.
- Caregivers must be matched based upon skill, service plans must be thoroughly reviewed with each caregiver before the initial delivery of care, and caregivers must provide care based upon the service plan.

**Medication services (OAR 333-536-0075)**
- A registered RN must evaluate a client’s medication regimen and the provision of medication administration services must be conducted and documented at least every 90 days for each client receiving medication administration services.
- Agency caregivers assigned to provide medication services must be given basic non-injectable mediation training before providing services and demonstrate appropriate and safe techniques. See rule for training standards.
- An individual with a current Oregon State Board of Nursing medication aide (CMA) certification is exempt from the training requirements under OAR 333-536-0075.

**Nursing services (OAR 333-536-0080)**
- If an agency is approved to provide nursing services, the services must be provided by an Oregon licensed registered nurse employed by the agency and provided only to a client whose medical condition and health status is stable and predictable.

**Service plan (OAR 333-536-0065)**
- The administrator or designee must conduct an initial visit at the client’s residence within 30 days of the initiation of services to evaluate compliance by caregivers with the service plan and to assess client’s satisfaction. The initial visit must occur between the 7th and 30th day, except when the client cancels service on or before the 30th day; the client is residing in a nursing home or a hospital; or the client refuses.
- The administrator or designee must conduct quarterly monitoring visits after the first site visit. Quarterly monitoring visits may occur by phone or other electronic means if impending discharge from services; relocation to a facility; when minimal services (one month shift) would cause the client to incur undue financial burden, or due to other circumstances justified in the chart.
- In no case shall the time between in-person monitoring exceed 6 months.
- See OAR 333-536-0065 for other site visit requirements, including the caregiver being present during the monitoring visit, determining whether appropriate and safe techniques have been used.

**Clients’ rights (OAR 333-536-0060)**
- The owner or administrator shall ensure that the agency recognizes and protects the clients’ rights as set forth in OAR 333-536-0060.
- Key rights include:
  - The right to voice grievances or complaints regarding services or any other issue without discrimination or reprisal for exercising such rights; and
  - The right to receive a notice of the clients’ right, which must include procedures for filing a grievance or complaint with the agency, the Division, and notice that the Division has the authority to examine clients’ records as part of the regulation and evaluation of the agency.

**Quality improvement (OAR 333-536-0090)**
- Agencies must establish and maintain effective, agency wide quality assessment and performance improvement program that evaluates and monitors the quality, safety, and appropriateness of services provided by the agency, which include at a minimum:
  - Method to identify, analyze and correct adverse events;
  - A method to select and track quality indicators by high risk, high volume,
problem prone areas and by the effect on client safety and quality of care;

- The quality improvement activities shall be conducted by a committee comprised of, at a minimum, agency administrative staff, an agency caregiver, and if the agency is classified as an intermediate or comprehensive agency, an agency registered nurse; and

- Quality improvement activities shall be conducted and documented at least quarterly.

• **Complaint filing procedures** (ORS 443.355 & OAR 333-356-0042)

  - **Reporting**
    - An employee or contract provider who has knowledge of a violation of laws or rules of the Oregon Health Authority shall use the reporting procedures established by the home health agency, in-home care agency or caregiver registry before notifying the authority or other state agency of the inappropriate care or violation, unless the employee or contract provider:
      - “Believes a client’s health or safety is in immediate jeopardy; or
      - Files a complaint in accordance with the rules adopted by the Oregon Health Authority.”

    - Any person may make a complaint verbally or in writing to the Public Health Division of the Oregon Health Authority. OAR 333-356-0042

    - If a complaint involves an allegation of criminal conduct or an allegation that is within the jurisdiction of another local, state, or federal, agency the Division shall refer the matter to that agency. OAR 333-356-0042

• **Confidentiality**

  - The information obtained by the Oregon Health Authority during an investigation of a complaint or reported violation is confidential and not subject to public disclosure.

  - Upon conclusion of the investigation, the Oregon Health Authority "may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any client of the home health agency, in-home care agency, or caregiver registry.”

  - The Oregon Health Authority may use the information obtaining during an investigation in an administrative or judicial proceeding.

• **Investigations** (OAR 333-356-0043)

  - “An unannounced complaint investigation shall be carried out within 45 calendar days of receipt of the complaint and may include, but is not limited to:
    - Interviews of the complainant, caregivers, clients, a client’s representative, a client’s family members, witnesses, and agency management and staff;
    - On-site observations of the client(s), staff performance, client environment; and
    - Review of documents and records.”

  - If the complaint allegation represents an immediate threat to the health or safety of a client, the Division shall notify appropriate authorities and the investigation shall commence within two working days.

  - An agency must permit Division staff access during the investigation and must cooperate with all investigations of allegations of client abuse and neglect.

• **State action for injunction; operation without valid license** (ORS 443.327 & OAR 333-536-0105)

  - The Oregon Health Authority may “maintain an action in the name of the state for injunction or other process against any person to restrain or prevent the establishment, conduct, management or operation of an in-home care agency without a license.”

  - Attorney fees and court costs may be recovered.

  - If an in-home care agency is found to be operating without a valid license, it must provide notice to its clients in a manner and time set forth by the authority. It can no longer provide services to the client and must refund all fees collected for services rendered. OAR 333-536-0105

• **Grounds for denial, suspension or revocation of license** (ORS 443.325 & OAR 333-356-0033)

  - Failure to comply with in-home care agency related ORS & OAR provisions may result in denial, suspension, or revocation of license.
Noncompliance includes, but is not limited to:

- “Failure to provide a written disclosure statement to the client or the client’s representative prior to in-home care services being rendered; failure to provide the contracted in-home care services; or failure to correct deficiencies identified during an inspection by the authority.” ORS 443.325
- An owner or administrator of the in-home care agency permitting, aiding or abetting any illegal act affecting the welfare of the client. OAR 333-356-0033
- Failure to comply with ORS 443.004 – background checks. OAR 333-356-0033
- Civil penalties may be imposed as well. ORS 443.325

**Violations** (OAR 333-536-0110)

- “In addition non-compliance with any law that governs an in-home care agency, it is a violation to:
  - Refuse to cooperate with an investigation or survey;
  - Fail to implement an approved plan of correction;
  - Refuse or fail to comply with an order issued by the Division;
  - Refuse or fail to pay a civil penalty;
  - Fail to comply with rules governing the storage of records following the closure of an agency;
  - Fail to report suspected abuse of elderly persons as defined by ORS 124.050;
  - Fail to return a license per OAR 333-536-0035;
  - Operate without a license.”

**Informal enforcement** (OAR 333-536-0117)

- During an investigation or survey, the Division may issue a statement of deficiencies and the agency has the opportunity to dispute the findings.
- Whether the agency disputes the findings or not, the agency must mail a signed plan of correction to the Division within 10 business days from when the statement of deficiencies was received by the agency. The correction plan will not be used as an admission of the violations alleged in the statement of deficiencies.
- Whether the agency disputes the findings or not, the agency must correct all deficiencies within 60 days from the date of the exit conference unless an extension is granted by the Division.
- The Division may request a corrected or modified plan if it is unacceptable.
- If the agency does not comply by the date of correction, the Division may propose to deny, suspend or revoke the agency license or impose civil penalties.

**Formal enforcement** (OAR 333-536-0120)

- If the Division finds substantial failure to comply with in-home care licensing laws or rules, or if the agency fails to pay a civil penalty imposed, the Division may issue a Notice of Proposed Suspension or Notice of Proposed Revocation.
- The Division may issue a Notice of Imposition of Civil Penalty for violations of in-home care licensing laws.
- The Division may issue a Notice of Emergency License Suspension under ORS 183.430(2).
- If an agency’s license is revoked, the order must specify if the agency may reapply.
- The Division may reissue an agency license that has been suspended or revoked after the Division determines that compliance with these rules has been achieved.

**Civil penalties** (OAR 333-536-0125)

- A civil penalty may not exceed $1,000 per violation and may not total more than $2,000.
- An individual who operates an in-home care agency without a license is subject to a civil penalty not to exceed $500 a day per violation.
- Factors in determining the amount of the civil penalty include:
  - The Division made repeated attempts to obtain compliance;
  - The licensee has a history of non-compliance with in-home care licensing laws and rules;
  - The violation poses a serious risk to the public’s health; and
  - There are mitigating factors, such as the licensee’s cooperation with the investigation or actions to come into compliance.
- Each day the violation continues is an additional violation.
APPENDIX B
PowerPoint Slides

OREGON IN-HOME CARE AGENCY REGS
Licensure requirements;
On-site inspections by state officials every 3 years
  - interviews of staff; review client files, personnel records, quality improvement plans, policies & procedures;
Background checks every 3 years
  - long list of disqualifying offenses;
Caregiver qualifications & training requirements;
Require client service plans & monitoring visits by IHCA administrators;
Complaint filing procedures;
Formal & informal enforcement + penalties

OREGON IHCA KEY FACTS
Has 128-130 IHCA.
About 30 very small, serving handful of clients.
2 full-time surveyors & 1 part-time surveyor
IHCA surveys take 2 full days
Fines imposed only twice in recent memory, only with license revocation.
Too burdensome b/c parties can appeal.
IHCA required only to formulate corrective action plans for deficiencies
  - no penalties imposed for failure to develop strong corrective plans or to adhere to them.

HOW CAN REGULATORY COMPLIANCE BE IMPROVED?
Numerous violations found at each survey
No possibility of hiring more enforcement staff or increasing resources
Think of way to both facilitate compliance and deter misconduct

Acknowledgement
Support for the Scholars in Residence fellowship program was provided by the Robert Wood Johnson Foundation.

References
Introduction

The information contained in this teaching module and the accompanying PowerPoint slides is appropriate for use in a survey public health law course or seminar. The purpose of this lesson is two-fold. The first objective is to provide law students with an overview of the authority public health agencies have to set and enforce policies necessary to keep the population healthy. The second objective is to inform law students about the legal constraints courts have placed upon the actions of those agencies. The module ends with a project designed to give law students the opportunity to apply the law to a “real world” situation.

Students need to understand that a public health course is different from a public health law course. Public health courses focus upon the manner in which public health agencies respond to incidents that may negatively impact the health of members of the public. On the other hand, public health law courses are designed to analyze the legal powers and duties given to public health agencies, so that they can perform their responsibilities. In addition, students enrolled in public health law courses will learn about the restrictions put on public health agencies that to protect the autonomy, privacy, liberty, proprietary and other interests of citizens.

States have a responsibility to protect the health of their citizens. Most states delegate that duty to public health agencies. The states’ public health authority comes from the police powers granted by state constitutions and reserved to them by the Tenth Amendment to the United States Constitution. When it upheld a law mandating small pox vaccinations, the United States Supreme Court stated “….the state may invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and public safety.”

The main goals of a public health agency are the following:

1. understand potential threats to the public health;
2. identify a policy for eliminating or reducing the threat;
3. implement that policy; and
4. evaluate the policy’s outcomes.

The purpose of public health law is to define the jurisdiction of public health officials and to specify the manner in which they may exercise their authority. In their quest to protect or promote community health, states have to take steps to protect the interests of their populations. Thus, legal limits constrain public health interventions as follows:

1. The actions proposed by the agency must be needed to thwart an avoidable public health threat.
2. A reasonable relationship must exist between the planned intervention and the achievement of a legitimate public health objective.
3. The human burden triggered by the intervention must be comparable with the anticipated benefit to the public, and
4. The intervention must not endanger the public’s health.

Class Structure
This exercise works best in a class of between 25 and 30 students so that each group can contain at least five students, but it can be adapted for use in larger and smaller classes. The students should be divided up into public health departments, each with a designated director. I focus upon the following types of catastrophes:

1. Natural disasters,
2. Manmade disasters,
3. Communicable diseases,
4. Antisocial behaviors, and
5. Lifestyle choices.

Natural disasters include things like earthquakes, fires, floods, hurricanes and tornados. Professors should focus upon the natural disasters most common in their area. Manmade disasters mainly refer to bombings and bioterrorism. The items that I place in the communicable diseases categories will vary depending on what is happening in the world at the time. For example, current areas of concern focus on Ebola, measles and influenza. The activities included in the antisocial behavior group include bullying, mass shootings and school shootings. Lifestyle choices that could lead to the need for public health intervention include obesity, prescription drug abuse, and small cigar smoking, but these lists are not exhaustive. Professors can add other categories as they deem appropriate for the class.

Students need to understand that a public health course is different from a public health law course. Public health courses focus upon the manner in which public health agencies respond to incidents that may negatively impact the health of members of the public.

The professor should then discuss the actions local public health departments can take to protect the public in these situations. Those acts include preparedness, response, mitigation, and recovery. A prime example of a preparedness activity is the creation of an emergency preparedness plan. The need for this type of action was highlighted by events like the city of New Orleans’ poor reaction to Hurricane Katrina in 2005 and the city of Dallas’ inadequate handling of the 2014 Ebola case.

After a disaster occurs, the local public health department has to be able to put its plan into action to respond. The manner in which the department responds to the crisis depends on the nature of the activity that caused the emergency. For instance, the public health department’s response to an outbreak of the West Nile virus will be different from its reaction to an increase in small cigar smoking.

A key component of a public health department’s response to disaster involves mitigation. Mitigation entails cooperating with law enforcement and other agencies to reduce the damage caused by the particular public health calamity.

The most difficult and time-consuming obligation of a public health department is to help the community recover in the aftermath of a disaster. Examples include the amount of time it took to clean up New York City and Oklahoma City after the bombings in those municipalities.

After the groups have been assigned their particular public health emergency, the professor should explain the possible legal challenges that may be filed against a public health department as the result of an intervention. Most of those challenges will be based upon state and federal constitutional law. (This would be a good time for the professor to hand out copies of his or her public health statutes and relevant state constitutional provisions for the students to review.)

The professor should then discuss how the First, Second, Fourth, and Fourteenth Amendments may be implicated by a public health intervention. For instance, a resolution to ban tobacco advertising near schools may be challenged on First Amendment grounds. Likewise, if the public health department seeks to prohibit the selling of guns near schools, vendors may bring a Second Amendment challenge. Opponents of mandatory HIV screenings may argue that the screenings are illegal searches and seizures in violation of the Fourth Amendment. Involuntary quarantines in response to events like the recent Ebola scare may be viewed as a violation of the Fourteenth Amendment.
Amendment’s protection against deprivation of liberty without due process. The professor should explain that, in addition to constitutional challenges, public health interventions may be contested based upon the right to privacy, statutory preemption, medical battery and lack of informed consent.

Exercises
The students in each public health department should:

1. Create an emergency preparedness plan to prepare for the crisis assigned to them.
2. Write a memorandum indicating the manner in which they will respond in the event the disaster actually happens.
3. Include steps that they will take to mitigate the damage caused by the calamity.
4. Prepare a memorandum identifying and addressing possible legal challenges to their proposed actions, and
5. Prepare a list of questions that need to be answered about what will happen prior to the event, during the event and after the event.

Scenario I: Natural Disaster Group
The National Weather Service has predicted that a weather-related natural disaster (the type depends on those common to the region where the students are located) will hit your city in approximately 72 hours. If the prediction is correct, the city will suffer severe loss of life and property damage. The students should gather relevant demographic information about their city. After the students complete the assignment, the professor should give the students a copy of the city emergency preparedness plan for comparison purposes. The professor may also show the students, “When the Levees Broke: A Requiem in Four Acts,” Spike Lee’s documentary on Hurricane Katrina. The purpose of showing the movie is for the students to understand the importance of having adequate plans in place to protect the public from the devastation that can occur as a consequence of a natural disaster.

Scenario II: Manmade Disaster Group
A confidential informant has told a local police detective that a radical group plans to put anthrax spores into the city’s water supply. The act is slated to happen three days after the police learn of the threat. The police take the threat seriously because anthrax spores were recently stolen from a local lab. The quantity of spores stolen is enough to contaminate the water within a five mile area of the primary water source. The professor should give the students a copy of the Centers for Disease Control and Prevention’s Bioterrorism Readiness Plan before they embark on the assignment set forth above.

Scenario III: Communicable Disease Group
The students in this group should be assigned the movie “Contagion” to watch. The movie involved the government’s efforts to locate the source of and to contain an Ebola-like virus. After watching the movie, in addition to the five steps in the general assignment for all groups, the students should evaluate the public health response to the outbreak as it was set forth in the movie.

Scenario IV: Antisocial Behavior Group
While surfing the web, a teacher at a local high school comes across a blog created by one of the students in her class. In the blog, the student stated that four students calling themselves Conquest, War, Famine and Death planned to kill seven people each on a school bus and then burn down the school. The teacher has reported her concerns to the police. The identity of the students and the targeted school is unknown. The city has five elementary schools, two middle schools and two high schools. The professor should refer the students to Guidelines for Responding to Student Threats of Violence by Dewey Cornell and Peter Sheras (Sopris West, 2006).

Scenario V: Lifestyle Choices Group
A non-profit group has performed a sting operation to determine the extent of small cigar smoking in the city. The group discovered the following:
1. Vendors sold small cigars to children without requesting identification;
2. Vendors displayed small cigars in the front of the store along with the candy and gum;
3. Vendors sold single small cigars;
4. Vendors gave “buy-one-get-one-free” coupons for small cigars; and
5. Vendors sold small cigars in “kid friendly” flavors like bubblegum and grape.

The group also conducted an online survey of middle and high school students. The survey results indicated that about 48% of middle school children and 77% of high school children smoke small cigars. The professor should direct students to the Tobacco Control Legal Consortium Fact Sheet Regulatory Options for Little Cigars, available at <http://publichealthlaw-center.org/sites/default/files/pdf/tclc-fs-regulatory-options-little-cigars-2013.pdf>.

Conclusion
This module will be helpful for professors who want to give students an overview of public health law. Professors may use the information contained in the module at the beginning of the course and refer to it periodically throughout the course. As the students gain more knowledge about public health law and policy, professors can modify the problems to cover various scenarios. If there is a particular public health issue that is in the news, the professor may ask the students to attempt to provide a solution based upon the law and policy taught in the class. The finished project could be circulated to the appropriate city official and/or the local public health department.

These exercises will enable students to think about public health law in a broad and concrete way. In addition to learning the law, the students will have the opportunity to collaborate with one another to create health policy. After the students complete the exercises, the professor may decide to share the students’ projects with members of the local public health department. In addition, the professor may decide to invite members of the local public health department to come to class and offer the students a critique of their work. For example, the students could compare their emergency preparedness plan to the one actually adopted by their city. Then, the professor could create an emergency scenario and have half of the students follow the student-created emergency preparedness plan while the other half follows the city-adopted emergency preparedness plan. After the emergency is over, the class could evaluate the outcomes and see which plan provided the most protection to the citizens.

Acknowledgement
Support for the Scholars in Residence fellowship program was provided by the Robert Wood Johnson Foundation.

References
These teaching materials explore the specific powers of governments to implement control measures in response to communicable disease, in two different contexts:

• The first context concerns global pandemic diseases. Relevant legal authority includes international law, World Health Organization governance and the International Health Regulations, and regulatory authority of nations.

• The second context is centered on U.S. law and concerns control measures for drug-resistant disease, using tuberculosis as an example. In both contexts, international and domestic, the point is to understand legal authority to address public health emergencies.

In the problem-based exercises that follow, students assimilate and closely read statutes and regulations, identify relevant global and federal governance structures, and role-play the decision processes of various government officials. Students are also encouraged to consider policy change and how it might be implemented to facilitate multi-government coordination to control communicable disease.

These exercises are designed for group or individual work by students which is then presented or reviewed in a classroom setting. I find it helpful to provide relevant materials to the students up front to avoid time-consuming research.

Although these materials are best suited for a course in global or U.S. public health law, some parts of the problem scenarios may be used in courses such as administrative law, advanced torts, immigration law, international law, or legislation and regulation. At the conclusion of the materials I have indicated how they may be modified for these courses.

Contents
• Overview
• Problem Scenario One: Responses to Pandemic Influenza
• Problem Scenario Two: Controlling Drug-Resistant Tuberculosis in the U.S.
• Variations for use in Other Courses

Overview
As practitioners and educators appreciate, but beginning students often do not, health law encompasses a broad array of statutes, regulations, and governmental agencies not traditionally grouped together. “Public health law” is a general term for the legal structures that apply, for example, to the recent outbreak of the Ebola virus in Guinea, Liberia, and Sierra Leone, along with the control measures to deal with Ebola patients in the United States. Some of these legal issues are internal to the nations involved, and some are external, or a matter of international law. These teaching materials provide an opportunity to canvass the many fields of law responsive to the threat of pandemic disease as well as control measures to combat development and spread of drug-resistant diseases such as tuberculosis.
Law students in particular should understand that an important part of preparedness for public health emergencies is “legal” preparedness. The Ebola virus outbreak in 2014 brought this issue to the forefront. I have chosen not to use Ebola as an example in these exercises, although instructors may wish to do so. Scientists worry more about new viruses that easily spread through the air, unlike the transmission of Ebola. Such new viruses, or mutations of old ones, could have the global reach and devastation of the Spanish influenza in 1918. Hence, I have chosen a form of avian flu for the teaching materials on pandemic outbreaks, but instructors may easily substitute another.

In the problem-based exercises that follow, students assimilate and closely read statutes and regulations, identify relevant global and federal governance structures, and role-play the decision processes of various government officials. Students are also encouraged to consider policy change and how it might be implemented to facilitate multi-government coordination to control communicable disease.

These two problem scenarios serve as a guide to the range of laws and regulations relevant to the treatment of communicable diseases as well as to the threat of antibiotic drug resistance. Students are provided the opportunity to address several questions:

- What role does the World Health Organization play?
- What aspects of international law apply?
- In the United States, how are quarantine orders issued and enforced?
- How do we balance the rights of individuals — who may be quarantined for weeks even if they display no symptoms of a disease — against public health concerns?
- What if public health authorities over-react and place large numbers of persons who are not sick into involuntary quarantine?
- How do nations, airports, and immigration officials deal with pandemic threats?
- What role does the CDC play at U.S. entry points?

Implementation of these legal structures, however, can be problematic between nations, federal governments, and in any community. Students should also appreciate that an understanding of the many regulatory aspects of health law, especially as applied to the containment of epidemic or endemic disease, can be an important tool to disseminate public information and to dispel misperception about health risks.

Problem Scenario One: Responses to Pandemic Influenza

In late December, reports of a chicken kill-off begin circulating in Fujian province, in the People’s Republic of China (PRC). PRC veterinarian inspectors begin investigating the occurrence, which is common in south China. It is quickly realized that the kill-off is attributable to a form of communicable avian influenza, which has a 100% mortality rate among infected animals. No other animals are affected, including wild ducks or other aquatic birds in the region. As per its normal practice, PRC officials declare a “safe-zone” region in Fujian and all surrounding provinces, order-

Three weeks later, in mid-January, Flu Watch, a non-governmental organization (NGO) based in Hong Kong, Bangkok, and Sydney, issues an advisory report indicating that at least one influenza death had been reported in both Fujian and Hong Kong, and that a suspected vector of infection has been identified as a possible avian virus that has crossed-over to humans. PRC authorities deny the reports: No human deaths, PRC authorities assert, are attributable to the chicken kill-off in Fujian province. As a response measure, the PRC announces a veterinary quarantine in south China and the forced elimination of all chickens in the affected region. Once again, the PRC asserts that there is no reportable event to WHO.

One week later, on February 2, Flu Watch again reports more human deaths: 3 in Fujian, 2 in Hong Kong, and 2 elsewhere in the region. Without revealing its sources and the content of its research, Flu Watch asserts that the infectious agent is a mutation of the H5N1 virus (“highly pathogenic avian influenza virus of type A of subtype H5N1”). This time, PRC officials denounce Flu Watch as “provocateurs” who are attempting to discredit PRC public health authority with spurious claims, inducing panic. Flu Watch agrees to submit its documentation to WHO, and the
PRC, for its part, invites a team of WHO investigators to Beijing for a consultation.

The WHO team is being assembled and is scheduled to arrive in Beijing on February 26. In the meantime, the Canadian government has announced a “special program” for travelers arriving in Canada (whether by sea or air) from south China. The special program applies to any international traveler who has been in South China since December 1. The special program requires that travelers submit to a medical examination to determine whether they are suffering from any flu symptoms. The examination does include mandatory blood-testing. The blood-test taken at the border can be completed within 72-hours, and is conclusive as to exposure to this mutation of H5N1 virus. The incubation periods for this mutation, the likely onset of the disease, and its progression, have not been scientifically established.

Specific elements of the “special program” in Canada:

1. Individuals at the Canadian border (including air or port terminals) who arrive from a Chinese destination, and who exhibit flu-like symptoms (any coughing or body temperature above 101°F [38.33°C]), will be subject to an immediate and mandatory quarantine.
   • Such quarantine shall be for no less than ten (10) days, even if the blood tests for the presence of the mutation of the H5N1 virus are negative or inconclusive.
   • Because of concerns about the effectiveness of home seclusion, the quarantine shall be at a public health facility or hospital.
   • The costs of any indicated medical treatment for the travelers, unless they are Canadian nationals, shall be borne by the travelers or their families.

2. For travelers at the border who do not exhibit any flu symptoms, and who remain in Canada instead of logging-in every 24-hours to a web-based program, they are required each day to visit a Canada Public Health facility and be subjected to a physical exam.
   • Follow-up blood tests may be required as part of these visits.
   • These visits are free of charge, and are not required after such time as it is conclusively determined (by the blood test) that the individual has not been exposed to the mutation of the H5N1 virus.
   • If, however, at a follow-up physical exam individuals exhibit flu symptoms they will be subject to the quarantine regimen outlined above.

Canada’s special program for travelers from China is immediately denounced by PRC officials. Nevertheless, other countries follow suit, adopting similar measures. Some countries have gone so far as to ban all travel by individuals from all of China. WHO has not issued any statements or directives.

Your Task

Simulation 1: You are an official of Public Health Canada, and have been asked to render an opinion on whether Canada’s proposed response is compliant with the letter and spirit of the WHO’s International Health Regulations (IHR) (2005).

Simulation 2: The United States government has made no decision about how to respond. The Surgeon General of the United States has asked you whether the U.S. Public Health Service should adopt Canada’s special program for travelers, or some variation thereof. What is your recommendation?

***

Instructor Notes and Resources

For any nation, including the United States, the starting point is international law — the laws governing the relationship and interactions of sovereign nations. Global governance of disease is a directive of the World Health Organization, based in Geneva. This scenario, then, is primarily based upon the International Health Regulations, which are available on the World Health Organization’s website.3

For context, I first direct students to this introductory statement from WHO:

Since 15 June 2007, the world has been implementing the International Health Regulations (2005). This legally-binding agreement significantly contributes to global public health security by providing a new framework for the coordination of the management of events that may constitute a public health emergency of international concern, and will improve the capacity of all countries to detect, assess, notify and respond to public health threats.4

Relevant sections include:

• Part IV: Ports of Entry; and
• Part V: Public Health Measures.
• See also IHR Implementation at Ports, Airports, and Ground crossings.5
Students are also given a brief overview of WHO’s response to the Ebola outbreak in western Africa, after it declared the situation to be an international public health emergency. This means that the International Health Regulations, adopted in 2007 to address significant contagious disease, apply to political, diplomatic, and trade relationships among 194 countries across the globe, including all the Member States of WHO. The International Health Regulations are designed “to help the international community to prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide.” This action is only the third time WHO has declared a global health emergency.

What response is required when the World Health Organization declares a “public health emergency of international concern,” the triggering language for application of the International Health Regulations? Primarily, the IHR provide a framework for global response designed to strengthen international public health security. WHO first issues temporary recommendations to address the emergency. These may include recommended measures for application by the nations most affected by an outbreak, as well as by other States and by operators of international transport. Recommended measures could be directed towards persons, cargo, ships, aircraft, road vehicles, and commercial goods.

In past outbreaks, WHO has recommended some travel restrictions, as was the case in 2009 with H1N1 influenza. Although WHO’s current recommendations for the Ebola outbreak do not include international travel restrictions, the declaration urged all nations where the disease is spreading to “declare an emergency, to screen all people leaving at international airports, seaports, and land crossings, and to prevent travel by anyone suspected of having the Ebola virus.” It also appealed to all member countries to devote resources and expertise to aid the most affected countries.

WHO’s recommended guidance included the following:

- Where extraordinary supplemental measures such as quarantine are considered necessary in States with intense and widespread transmission, States should ensure that they are proportionate and evidence-based, and that accurate information, essential services and commodities, including food and water, are provided to the affected populations.

WHO also stated:

- Flight cancellations and other travel restrictions continue to isolate affected countries resulting in detrimental economic consequences, and hinder relief and response efforts risking further international spread; the Committee strongly reiterated that there should be no general ban on international travel or trade, except for the restrictions outlined in the previous recommendations regarding the travel of EVD cases and contacts.

WHO declared that there should be no international travel of Ebola patients or persons in close contact with them, unless the travel is part of an “appropriate medical evacuation.” Nations experiencing Ebola transmission “should consider postponing mass gatherings until EVD transmission is interrupted.”

WHO Member States agreed upon the International Health Regulations by consensus as a balance between their sovereign rights and a shared commitment to prevent the international spread of disease. Although the Regulations do not include an enforcement mechanism for States which fail to comply with WHO recommendations, the potential consequences of non-compliance are themselves a powerful tool. These consequences may include a tarnished international image, increased morbidity/mortality in affected populations, unilateral travel and trade restrictions by other nations, and economic and social disruption. Working with WHO to control a public health event such as Ebola can help prevent reflexive, unnecessary, and counter-productive border closings and economic disruption.

Thus, “law” as we traditionally view it does not control how nations deal with each other in the event of a pandemic health threat. The International Health Regulations, however, are binding on member states, even as they emphasize coordination and voluntary cooperation. The aim is to avoid over-reactions that could have severe humanitarian consequences. Students should recognize that how the United States and other nations treat arriving passengers from disease-prevalent areas begins with this framework.

Instructors using the second variation, concerning potential U.S. policy, should note that substantial federalism issues may arise. Because I consider state and federal government divisions of authority in a separate problem scenario, I prefer to avoid them in this exercise by instructing students to ignore state authority over persons admitted into the U.S. and to assume that only federal law will apply. Instructors who wish
to include state as well as federal authority should refer to the notes following Problem Scenario Two.

Under 42 Code of Federal Regulations parts 70 and 71, CDC is authorized to detain, medically examine, and release persons arriving into the United States and traveling between states who are suspected of carrying these communicable diseases. Federal isolation and quarantine authority is authorized for specified communicable diseases and by Executive Order of the President.

These issues are developed in Problem Scenario Two below, and other relevant legal authorities on these issues are provided there.

Problem Scenario Two: Controlling Drug-Resistant Tuberculosis in the U.S.13

Mortality from drug-resistant tuberculosis is a significant global problem and is currently a “serious threat” for the United States, according to the CDC.15

The CDC warns that if infection rates of drug-resistant tuberculosis increase within the U.S., the threat will change “from serious to urgent” because it can be transmitted through the air and treatment options are very limited.16

Exposure to tuberculosis can be tested almost immediately. Such tests identify persons who have acquired “latent” tuberculosis, which may or may not develop into the active form of the disease. Persons with latent tuberculosis then receive medical care as appropriate.

Patient A has been diagnosed with active multidrug resistant TB (MDR-TB), a form of tuberculosis resistant to the most commonly used antibiotics. The following questions present different geographic locations for Patient A at the time of diagnosis.

**Questions**

1. Patient A has arrived at an international airport in the U.S.:
   - Which government agencies may be responsible for monitoring or detaining Patient A, and
   - Under what legal authority(ies)?
   - What issues of concurrent jurisdiction may apply to this situation?

2. If on-site medical assessment at the airport determines that Patient A’s condition warrants transfer to a hospital for further evaluation:
   - Which government jurisdictions and agencies may be responsible for managing his transportation to the hospital and covering associated costs?
   - Under what legal authority(ies)?
   - Who is responsible for tracing the patient’s contacts to identify persons potentially exposed to the disease?

3. Patient A is diagnosed within the state of Texas [or another state] by that state’s local public health department, which then instructs the patient to remain at home for daily visits by a health worker who provides medication and watches the patient take it. The patient, however, does not comply with these instructions, and is often not at home when the health worker arrives.
   - What is the process for the public health department to enforce its directive?
   - In addition to courts, what other agencies may be involved?

4. Patient A has evaded an isolation order issued by State 1, and is now located in State 2. To facilitate continuity in treatment of Patient A:
   - What legal authority(ies) can State 2 employ to incorporate or rely on State 1’s isolation order and procedures for confinement and treatment of Patient A, or
   - Will it be necessary to initiate an original and full proceeding in State 2? What state legal authority(ies) will apply in determining in which facility(ies) Patient A may be ordered for hospitalization, isolation, and treatment?
   - What legal authority(ies) will apply in determining coverage of costs and reimbursements to a health-care facility for providing care and treatment to Patient A for the duration of his hospitalization?

**Instructor Notes and Resources**

This scenario focuses upon federal and state public health authority — particularly the use of quarantine and isolation — in the United States. I have chosen the context of tuberculosis for two reasons. First, public health officials to date have more experience with quarantine and isolation for tuberculosis patients than any other disease. Second, patient non-compliance with the lengthy treatment regimen for tuberculosis is a leading cause of the development of drug-resistant tuberculosis, considered a “serious threat” in the United States by the CDC.
Students will immediately think of the Ebola virus. Tuberculosis is more easily spread, yet TB garners little attention in the media, except when local outbreaks result in deaths, as occurred recently at an Atlanta homeless shelter, or in El Paso Texas, when more than 800 persons, mostly infants, were tested for potential TB exposure through a health care worker. By comparison, health authorities tracked 48 persons in Dallas, Texas, after the diagnosis of a traveler who had developed Ebola.

This problem requires familiarity with some basic features of U.S. (federal and state) quarantine and isolation authority. A good overview is available from the CDC’s website, which I encourage students to review first.

I also provide in a handout the following:

All U.S. states provide for isolation or quarantine by statute. As the CDC explains, the two terms have different technical definitions:

**Isolation** separates ill persons who have a communicable disease from those who are healthy. Isolation restricts the movement of ill persons to help stop the spread of certain diseases. For example, hospitals use isolation for patients with infectious tuberculosis, and patients may be requested to observe in-home isolation.

**Quarantine** separates and restricts the movement of well persons who may have been exposed to a communicable disease to see if they become ill. These people may not be aware of exposure to a disease, or they may have the disease but do not show symptoms.

Contact tracing inevitably compromises privacy rights about a patient’s condition. Public health officers have statutory authority to reveal a patient’s condition to those potentially exposed, although the patient’s name or other identifying information generally may not be disclosed publicly. Hospitals and private health care providers are obligated to inform local public health departments when they diagnose certain contagious diseases and may be required to provide the names of the patient’s potential contacts that they know about.

The CDC provides a compilation of state laws for tuberculosis control, an excellent resource for state-specific variations.

Although the U.S. legal system has substantial experience with isolation orders for tuberculosis, quarantine orders for those who may have been exposed are not used. Instead, public health officials trace contacts of anyone diagnosed with active tuberculosis, offering but not mandating screening for those persons. Isolating patients thought to be contagious is a routine process in the U.S. for diseases such as tuberculosis, and that process illustrates the limited judicial role.

A recent example from Georgia illustrates legal enforcement when needed for a tuberculosis patient who refuses to comply with a public health order. Local public health officials documented the failure of a TB patient to comply with an agency order for isolation and directly observed therapy. The public health agency presented evidence of his non-compliance to a county court, which then issued an arrest order. The patient was held in an isolation facility in the county’s prison until he was no longer contagious.

Who is in charge? The federal government acts to prevent the entry of communicable diseases into the United States. Quarantine and isolation may be used at U.S. ports of entry. USPHS is authorized to take measures to prevent the spread of communicable diseases between states.

- May accept state and local assistance in enforcing federal quarantine.
- May assist state and local authorities in preventing the spread of communicable diseases.

State, local, and tribal authorities enforce isolation and quarantine within their borders. It is possible for federal, state, local, and tribal health authorities to have and use all at the same time separate but coexisting legal quarantine power in certain events. In the event of a conflict, federal law is supreme.

**Enforcement:** If a quarantineable disease is suspected or identified, CDC may issue a federal isolation or quarantine order. Public health authorities at the federal, state, local, and tribal levels may sometimes seek help from police or other law enforcement officers to enforce a public health order.

Thus, with scenario two the instructor may wish to provide relevant state quarantine legislation. In addition to the CDC compendium noted above, individual state summaries are available from the National Conference of State Legislatures and the Centers for Law and Public Health. (A variation on this is to present the Model State Emergency Health Powers Act, also available online.)

A practicum variation would ask a state health department attorney to prepare an initial quarantine order and other documents in seeking a court order. In some states, a public health officer is empowered to impose quarantine by issuance of a public health order, but in other states, judicial action is required.
For states in which judicial action is required, Texas law for TB control is a good example. A judicial order requires supporting affidavits from the appropriate public health agency, which the students could draft, in preparation for a court filing (complaint). In Texas, quarantine and isolation authority beyond 72 hours entitles a patient to a jury trial, and appointed counsel. Court-ordered management forms in Texas are available online.26

For Further Classroom Discussion
Some students may be interested in immigration-related aspects of question one (the question does not specify whether Patient A is a U.S. national or a citizen of another country). A helpful guide is a Congressional Research Service report, Immigration Policies and Issues on Health-Related Grounds for Exclusion.27

For example, instructors might ask one or more of the following questions:

• There may be statutory or administrative changes that would provide better disease surveillance at U.S. border points. What options might you recommend?
• Assuming greater border protection requires the expenditure of additional resources, who pays? How would an agency assess the cost versus benefit of the proposal?
• What about constitutional rights of both citizens and non-citizens? Consider also humanitarian concerns and the availability of health care. If a foreign national cannot afford necessary health care, that person may be excluded or deported as having become a “public charge.”28
• Is the CDC’s “do not board” list adequate, or could it also be used to prevent entry into the United States by other means of transportation?

Variations for Use in Other Courses
Although the preceding teaching materials are designed for use in courses in public health law, these problems can be modified for use in other courses. I provide suggestions below.

Torts (Advanced or Survey)
• Charitable immunity in public health emergency (check state statutes) against false imprisonment or other damages claim.
• Sovereign immunity in public health emergency (check state statutes; note that the Federal Tort Claims Act does not waive sovereign immunity for “Any claim for damages caused by the imposition or establishment of a quarantine by the United States.”)
• Patient Confidentiality
• Physician liability/immunity under state mental health commitment statute against false imprisonment claim.

Administrative Law or Legislation and Regulation
• A drafting exercise for quarantine authority or other public health measure, including both an authorizing statute and implementing agency regulations.
• Role-play: identify the decision-process for the head of an administrative agency, in response to one of the scenarios described above.

International Law
• Explore the authority of the World Health Organization and the applicability of the International Health Regulations. What is the role of NGOs?

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References
2. This problem scenario is adapted from materials provided to me by the late Professor David J. Bederman, Emory University School of Law.
4. Id.
10. See Cowling and Cumming-Bruce, supra note 8.
12. Id.

13. Parts of this scenario are based upon factual scenarios prepared by the CDC Division of Tuberculosis Elimination, available at <http://www.cdc.gov/phlp/docs/User%27s%20Guide%20for%20Implementing%20Scenario.pdf> (last visited June 10, 2015).


16. Id.


20. Id.


