<table>
<thead>
<tr>
<th>Inside This Issue</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, and Future</strong></td>
<td>Stephen P. Teret</td>
</tr>
<tr>
<td><strong>Assessing the Legality of Expedited Partner Therapy for STDs</strong></td>
<td>James G. Hodge, Jr., Erin Fuse Brown</td>
</tr>
<tr>
<td><strong>Pandemic Influenza: Ethical Allocation of Scarce Vaccines and Antivirals</strong></td>
<td>Lawrence O. Gostin</td>
</tr>
<tr>
<td><strong>The “New Public Finance” and Global Health</strong></td>
<td>David P. Fidler</td>
</tr>
<tr>
<td><strong>Global Health Governance Seminar Finds Challenges and Opportunities</strong></td>
<td>Scott Burris</td>
</tr>
<tr>
<td><strong>Environmental Public Health Tracking and the Law</strong></td>
<td>Lance A. Gable</td>
</tr>
<tr>
<td><strong>An Assessment of School Laws and Policies Concerning Child and Adolescent Health</strong></td>
<td>James G. Hodge, Jr., Julie Samia Mair, Lance A. Gable</td>
</tr>
<tr>
<td><strong>Center Comments on CDC’s Proposed Federal Quarantine Regulations</strong></td>
<td>Benjamin Berkman</td>
</tr>
<tr>
<td><strong>The Supreme Court and Violence Against Women: Challenges for Advocates</strong></td>
<td>Jon S. Vernick, Lainie Rutkow</td>
</tr>
</tbody>
</table>
Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, and Future

STEPHEN P. TERET

Vaccination of children against infectious disease is well recognized as one of the greatest successes of public health for dramatically reducing or eradicating previously major causes of morbidity and mortality. However, compulsory vaccination remains a contentious topic. Anti-vaccination sentiment appears to be growing in the United States, fueled by claims of serious adverse reactions among some children. Traditionally, a child can receive an exemption from a state law requiring immunization if he or she can demonstrate that the drug is medically contraindicated. Most states have also allowed for exemptions based on religious beliefs. Recently, state legislatures have been strongly lobbied for the additional creation of philosophical or conscientious exemptions, allowing parents to avoid immunizing their children merely because they object in principle.

[A lesson] learned . . . is that the allowance of exemptions to mandated vaccination may limit public backlash against the laws.

In the February 4, 2006 issue of The Lancet, Center Director Stephen P. Teret and co-authors published an article entitled “Compulsory vaccination and conscientious or philosophical exemptions: past, present and future.” It is based largely on the work of Dr. Daniel Salmon when he was a Johns Hopkins doctoral student advised by Professor Teret.

For more information, see Salmon DA, Teret SP, MacIntyre CR, Salisbury D, Burgess MA, and Halsey NA. Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. The Lancet 2006; 367:436-42.

Assessing the Legality of Expedited Partner Therapy for STDs

JAMES G. HODGE, JR. AND ERIN FUSE BROWN

Effective clinical treatment of certain sexually transmitted diseases (STDs) (e.g., chlamydia and gonorrhea) may require treatment of patients’ current sex partners to prevent reinfection and further transmission. Traditional practices to reach at-risk sexual partners of persons infected with STDs include partner notification and provider-assisted referrals. However, public health practitioners are increasingly reviewing the utility of a new public health technique known as expedited partner therapy (EPT). EPT involves the direct delivery of medications or prescriptions by persons infected with an STD to their at-risk sexual partners. No clinical assessment of the partners is required, thus eliminating an existing barrier for some partners who might need treatment but are unwilling to seek clinical care.

The use of EPT as a standard public health practice presupposes that it is legally permissible across jurisdictions. However, the legality of EPT in many jurisdictions is uncertain. At the crux of legal concern is the potential unauthorized distribution of prescriptions by clinicians to persons (partners) without a personal evaluation or doctor-patient relationship. Although antibiotic treatment for some STDs offers few adverse risks to patients, the lack of a formal clinical evaluation raises questions about the legal permissibility of EPT. Concerns about potential liability, professional ethics, and medical licensing status pervade the implementation of EPT through public and private health care workers.

The Center for Law and the Public’s Health is partnering with CDC’s National Center for HIV, STD, and TB Prevention (NCHSTP) to assess the legal and policy issues concerning EPT for STDs across the states and additional jurisdictions. Some states have statutorily authorized the practice of EPT. However, most states’ laws do not directly resolve questions of the legality of EPT. The Center and NCHSTP have developed a national legal assessment to formulate policy and public health strategies to enlist key partners, agencies, and officials to explore the practice EPT and overcome the legal and policy barriers to its wider implementation.

For more information, please contact James G. Hodge, Jr., Center Executive Director.
Pandemic Influenza: Ethical Allocation of Scarce Vaccines and Antivirals

LAWRENCE O. GOSTIN

Governments have placed great emphasis on medical countermeasures, such as vaccines and antivirals, in their planning for pandemic flu. Yet, there will almost certainly be an extreme scarcity of countermeasures in the short-term. The most challenging question facing bioethics is how to ration scarce life-saving resources.

1. Prevention/Public Health. The historic mission of public health is prevention, so countermeasures to impede transmission should be a high priority. Where feasible, rapid deployment of vaccines or prophylaxis to groups at risk of acquiring infection should be used to contain localized outbreaks.

2. Scientific/Medical Functioning. If the first political priority is public health, then it is essential to protect individuals who innovate, produce vaccines or antivirals, provide treatment, and protect the public’s health. Consequently, priority should be given to key personnel developing countermeasures, delivering health care, and devising public health strategies.

3. Social Functioning/Critical Infrastructure. In a large-scale pandemic, key sectors of society may not be able to function. Many public and private agents are necessary for the public’s health and safety: first-response, security, essential products/services, critical infrastructure, and sanitation.

4. Medical Need/Vulnerability. Medical need is a widely accepted rationing criterion. The objective of reducing serious illness and death among individuals, therefore, targets those most vulnerable.

5. Social Justice/Equitable Access. The allocation of benefits should not favor the rich, powerful, or politically connected. The Gulf Coast hurricanes seared into the American consciousness the inequities that could ensue in a public health emergency—evacuation and relief services disfavored the poor and minorities. Special efforts, therefore, should be made to ensure fair distribution of life-saving countermeasures to prevent pandemic influenza.

6. Global Perspective. Realistically, resources will go to those countries where products are owned and manufactured. This reality can have devastating consequences for resource-poor countries that cannot compete economically for expensive countermeasures. Consequently, there is a strong moral justification for fair rationing from a global perspective. Even from a less altruistic perspective there are reasons to invest in poor regions. Improved surveillance and response can help in early detection and containment of outbreaks, affording universal benefits.

Planning for an influenza pandemic is vital to success and one of the most important social functions is to ensure fair allocation of scarce resources.

This commentary is derived from Part I of a two-part series in JAMA: Gostin LO. Pandemic Influenza: Ethics, Law, and the Public’s Health – Medical Countermeasures. JAMA 2006; 295:554-556. Part II, on public health interventions, is forthcoming.

The “New Public Finance” and Global Health

DAVID P. FIDLER

A frequent lament in global health regards the shortage of financial resources. Money for global health typically flows from governments or private organizations. Noting changes in this pattern, the UN Development Programme (UNDP) recently highlighted the emergence of the "new public finance" (NPF), which has implications for global health.

The NPF idea asserts that the traditional silos of "public" and "private" funding for development are inadequate. New mechanisms for raising more funds are needed. NPF strategies seek to integrate public and private capital in ways different from traditional aid channels and even from other innovative efforts, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

One health-specific NPF mechanism is the International Finance Facility for Immunization (IFFIm). IFFIm will raise funds from private investors by selling bonds on capital markets. Legally binding, long-term commitments from donor governments provide the security for bond repayment at maturity. The strategy accesses private capital to fund rapid immunization expansion in the developing world, with donor governments paying private investors later when the bonds mature. Experts predict that using private capital to quickly expand immunization efforts could produce significant health, development, and human security benefits.

Interest in IFFIm is genuine, but policy and legal questions remain. Eventually, governments will have to pay private investors their principal and accrued interest, perhaps creating demands that such public funds be channeled into global health instead of private capital markets. How current long-term financial pledges by governments will be legally binding in 15-20 years remains unclear.

Nevertheless, the NPF movement and IFFIm bear watching as creative efforts to improve global health continue.
**Global Health Governance Seminar Finds Challenges and Opportunities**

**SCOTT BURRIS**

The Salzburg Seminar on the Global Governance of Health was held in December, 2005, at Schloss Arenberg in Salzburg, Austria. Center Associate Director Scott Burris co-organized the meeting, which also featured a keynote address by Center senior scholar David Fidler. The gathering, sponsored by the Open Society Institute, brought together 40 global thinkers and leaders in public health, health services delivery, health policy, and academia. The Seminar consisted of two days of intensive discussion of the current state of health governance, followed by two days of collaborative brainstorming on new initiatives in governance practice, research, and theory.

Over the course of the Seminar, the group clearly agreed that governance was important, timely, and unduly neglected. Ranging in scope from municipal to global levels, presentations and comments laid out a complex picture of factors that limit the impact of efforts to protect and promote a higher level and fairer distribution of good health around the world. There was wide agreement that most of the pivotal issues—including inefficient resource allocation, corruption, top-down program design, lack of coordination, and insufficient involvement of civil society—could profitably be conceived as failures of governance. Despite this agreement, attendees had much difficulty arriving at a consensus on what terms or indicators to use to conceptualize and remedy these failures. This struggle paved the way to constructive ideas about the necessary next steps for an initiative to improve the global governance of health.

Five themes emerged from these proceedings: (a) this is a time of opportunity for meaningful change in the governance of global health programs; (b) the governance of health at the global level is weak and coordination is poor; (c) participatory rhetoric from powerful actors has fallen short of giving stakeholders and civil society a meaningful role in decision-making; (d) despite the rise in funding and interest in disease-specific programs, the core mission of promoting population health and improving health systems is being obscured; and (e) major empirical and political work is needed to improve the governance of global health programs.

Participants suggested a comprehensive, well-coordinated program of action in which health leaders, practitioners, researchers, and civil society stakeholders would:

1. Design and implement strategies to mobilize global health leaders to improve governance internally—in their own organizations—as well as the system on the whole;
2. Develop strategies and build coalitions for boosting support among global elites for stronger public health institutions and global governance architecture built on a properly funded “anchor” institution;
3. Provide proper mechanisms of representation and organization of civil society in global health architecture, including re-sourcing civil society at the local level to participate effectively, and re-thinking current frameworks (such as the Global Fund’s CCM) from a governance standpoint; and
4. Conduct interdisciplinary research to advance systematic measurement of governance, and identify or develop models of good health governance at the local, national, and international levels.

Conference materials are available at www.healthgov.net.

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**Environmental Public Health Tracking and the Law**

**LANCE A. GABLE**

The Center has been working with the state of Montana to develop the relationship between law and Environmental Public Health Tracking (EPHT). The concept of EPHT is rooted in efforts to assess the effects of exposures to environmental hazards on public health outcomes. While substantial evidence of this linkage exists, public health surveillance data, environmental hazard data, and exposure monitoring data have not been utilized in an integrated effort. Cooperation could facilitate tracking of the associations between environmental factors and health outcomes or development of prevention and intervention strategies to reduce the health risks of environmental exposures.

*A successful EPHT program demands a robust information infrastructure to track relevant environmental factors and analyze their impact on population health.* State statutes and regulations are key to the development of this information infrastructure. State laws may augment or limit the ability of state agencies to acquire, use, retain, or disclose data on environmental hazards, environmental exposures, and health human effects.

The Montana project will address laws that facilitate or limit the acquisition of data (surveillance, reporting, access to existing databases) and their use (sharing of data between agencies, comparing databases, disclosure to entities outside state government, data privacy). To fully implement EPHT, government agencies may require additional legal authority to acquire and use needed information. Simultaneously, they will have to respect privacy and proprietary concerns related to these data. Efforts to maintain good data stewardship should not be a barrier to EPHT.
An Assessment of School Laws and Policies Concerning Child and Adolescent Health

JAMES G. HODGE, JR., JULIE SAMIA MAIR, AND LANCE A. GABLE

Protecting the health and safety of children, adolescents, and others in school environments is an essential but challenging component of any comprehensive public health plan. The nation’s public schools are regulated through a multitude of federal, state, and local governmental entities that lack cohesion in their collective approach to improving child and adolescent health in educational settings. As in many areas of public health, the law can be an important tool for integrating policies and improving health outcomes of children and adolescents in schools.

To date, however, no one has systematically assessed school laws, regulations, and policies that seek to protect child and adolescent health. Together with CDC’s National Center for Chronic Disease Prevention and Health Promotion, Division of Adolescent and School Health (DASH) and CDC’s Public Health Law Program, the Center is developing a modern legal framework for the role of law in protecting the health of students and staff in the nation’s public schools (grades K-12).

The culmination of the Center’s research is the production of a blueprint outline (which has been shared with national educational and public health partners) and a comprehensive White Paper (currently in draft). These documents are based on the eight interactive components of DASH’s coordinated school health program (CSHP): (1) health education, (2) physical education, (3) health services, (4) nutrition services, (5) counseling and psychological services, (6) healthy school environment, (7) health promotion of staff, and (8) family/community involvement. Underlying these components are constitutional, statutory, regulatory, and judicial laws and policies that regulate (directly or indirectly) student and staff health and safety in schools at all levels of government.

The primary goal of the Center’s research and forthcoming White Paper is to increase understanding and foster collaboration on the use of school-related legal interventions to improve child and adolescent health through governmental and private sector entities.

For more information about this project, please see the Center’s website at www.publichealthlaw.net/Research/Affprojects.htm.

Center Comments on CDC’s Proposed Federal Quarantine Regulations

BENJAMIN BERKMAN

The federal government has a major interest in protecting American citizens from the threat of communicable diseases. In response to the recent SARS and West Nile Virus outbreaks, combined with the impending threats of pandemic influenza and bioterrorism, CDC has proposed new federal quarantine regulations. These regulations are designed to strengthen and clarify the federal power to prevent the spread of infectious diseases entering the United States, crossing state lines, or threatening national security.

In comments submitted to CDC, the Center commends this effort to strengthen and modernize one of the essential tools of public health law that may be needed in response to national public health emergencies. However, the Center also addresses the concerns raised by the proposed regulations.

While the government must possess the ability to quarantine, such power must be limited. The government must carefully balance not only individual and communal interests but also domestic and international law. The proposed regulations fail to maintain these balances. In particular:

- Government accountability needs to be strengthened by more specifically articulating the bounds of federal quarantine authority;
- Individual rights should be protected by requiring the federal government to provide and pay for safe, humane conditions; the necessities of life; and adequate medical services;
- Individual due process provisions must be reinforced, particularly by adding an independent judicial review procedure;
- Detailed privacy standards are needed to ensure fair health informational practices; and
- U.S. government authority and U.S. international legal obligations must be coordinated.

The Center’s comments were prepared by Lawrence O. Gostin, Benjamin Berkman, and David P. Fidler, and are available at http://www.cdc.gov/ncidod/dq/nprm/viewcomments_jan.htm.
The Supreme Court and Violence Against Women: Challenges for Advocates

JON S. VERNICK AND LAINE RUTKOW

Violence against women has increasingly been recognized as a critical problem for both the public health and legal systems in the United States. Each year in the U.S., approximately 1200 women are homicide victims. Forty (40) to fifty (50) percent of these women are killed by an intimate partner. The estimated lifetime prevalence of intimate partner violence (IPV) against women is 25-30%.

Many different legal interventions have been introduced to reduce the rate of intimate partner violence. Recently, a number of these interventions have been scrutinized by the Supreme Court. For example, in United States v. Morrison, 529 U.S. 598 (2000), the Court invalidated a portion of the federal Violence Against Women Act of 1994 on commerce clause grounds. The Act had provided victims of gender-motivated violence with a cause of action against their abuser.

Similarly, in Castle Rock v. Gonzales, 125 S. Ct. 2796 (2005), a woman sued the town of Castle Rock, Colorado for its failure to enforce an existing restraining order against her estranged husband. He subsequently murdered their three children. The Court concluded that the woman did not have a protected property right in the enforcement of her restraining order, and therefore dismissed her lawsuit.

These and other recent Supreme Court decisions have created challenges for IPV advocates. In an ongoing project, Center colleagues are examining the implications of these court decisions. Recommendations for advocates and practitioners are being developed to respond to the challenges and limitations posed by the Court.

**Publications (Select)**

**Lawrence O. Gostin**

Gostin LO. Pandemic Influenza: Ethics, Law, and the Public’s Health – Medical Countermeasures. JAMA 2006; 295:554-556.


**Stephen P. Teret**

Salmon DA, Teret SP, MacIntyre CR, Salisbury D, Burgess MA, and Halsey NA. Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. The Lancet 2006; 367:436-42.

**James G. Hodge, Jr.**


**Jon S. Vernick**


**David P. Fidler**


**Lance A. Gable**


**Center Announcements**

The Center is convening a panel discussion on “Avian Influenza: Legal and Policy Implications,” at the Georgetown Infectious Disease Conference, Georgetown University, on February 27, 2006. Lance Gable, Chair, will be joined by Benjamin Berkman and James G. Hodge, Jr.

The Center is co-sponsoring with the Johns Hopkins Center for Public Health Preparedness and the Phoebe R. Berman Bioethics Institute a leadership summit on legal and ethical issues in public health emergency responses on June 29, 2006 in Washington, DC.