



CENTER INSIGHTS

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Health of the People: The Highest Law*

Lawrence O. Gostin

In this inaugural issue of *Center Insights*, it is fitting to reflect on where the field of public health law has been and is heading. Once fashionable during the Progressive era, the ideals of population health began to wither with the rise of liberalism in the late 20th century. In its place came a sharpened focus on personal and economic freedom. Political attention shifted from population health to individual health and from public health to private medicine.

Signs of revitalization of the field of public health law can be seen in diverse national and global contexts: the creation of centers of excellence in public health law such as our Center, reform initiatives for national public health laws, and renewed interest in global governance of health threats.

The field of public health law encompasses at least three broad categories of law: national public health law, international public health law, and legal interventions to address particular public health concerns. National public health law encompasses the body of domestic legislation and regulation that creates the mission, functions, services, and powers of governmental public health agencies. These laws also contain restraints on state power to safeguard civil liberties. Na-

tional public health laws are frequently antiquated, built in layers over many decades. Late last year, the Robert Wood Johnson Turning Point National Excellence Collaborative published the Model State Public Health Act (see page 2). Similar efforts are ongoing in diverse national contexts ranging from Australia, Canada, and the United Kingdom to China and Singapore.

International public health law encompasses a body of diverse treaties and regulations designed to protect the health of the global community. This body of law relates, for example, to the trans-border spread of infectious diseases (e.g., International Health Regulations), food safety (Codex Alimentarius Commission), and smoking (the WHO's Framework Tobacco Convention). International law also protects civil and political, as well as social and economic, rights through the International Bill of Human Rights. Although international public health law often has weak standards and lax enforcement, efforts are underway to strengthen them. Notably, the WHO is currently revising the International Health Regulations in the aftermath of SARS and avian influenza (see <http://www.who.int/csr/ihr/en/>).

The third category of public health law involves the various legal tools to prevent or ameliorate discrete health threats. These include: 1) *direct regulation*—e.g., seatbelt and motorcycle helmet laws and bans on smoking in public places; 2) *indirect regulation*—e.g., tort actions against cigarette and firearm manufacturers; 3) *regulation of the built environment*—e.g., zoning and lead abatement; 4) *regulation of the informational environment*—e.g., restrictions on advertising of hazardous products; and 5) *taxing and spending*—e.g., cigarette taxes.

These important and difficult legal problems are part of the Center for Law & the Public's Health's agenda, as we collaborate with scholars and practitioners to promote the public's health and safety through law.

* This discussion is based on the Keynote Address presented at the conference, "Health of the People: The Highest Law?", 8 January 2004, Queen Elizabeth II Conference Centre, London, England. An expanded version appears in Lawrence O. Gostin, *Law and Ethics in Population Health*, 28 *Aust & NZ J Pub Health* 7 (2004).

"THE CARE OF HUMAN LIFE AND HAPPINESS, AND NOT THEIR DESTRUCTION, IS THE FIRST AND ONLY OBJECT OF GOOD GOVERNMENT" - THOMAS JEFFERSON (1809)

THE TURNING POINT MODEL STATE PUBLIC HEALTH ACT: A TOOL FOR ASSESSING STATE AND LOCAL PUBLIC HEALTH LAWS

JAMES G. HODGE, JR.

The Turning Point Public Health Statute Modernization Collaborative has recently issued its Model State Public Health Act (www.publichealthlaw.net/Resources/Modellaws.htm). Funded by the Robert Wood Johnson Foundation, the Turning Point Act was developed over multiple years in collaboration with national, state, tribal, and local public health officials, partners, and experts. The Act presents the most comprehensive series of model provisions of state public health law ever produced in the United States. As co-drafter of the Turning Point Act, let me share some brief insights on the scope of the Act itself.

The Turning Point Act provides model provisions on public health infrastructure, practice, and administration that are consistent with modern principles of law, ethics, and public health science. It builds an intersectoral public health system (consistent

with the Institute of Medicine's approach) that underlies the improved delivery, performance, and assessment of public health powers and duties.

Though extensive, the Turning Point Act does not cover all major areas of state public health law. For example, it does not broadly include environmental health services despite their strong public health relevance. It does not address all laws that directly impact (e.g., tobacco provisions, seatbelt laws) or are relevant to (e.g., mental health, health care services) the public's health. Nor does the general statutory language of the Act spell out details of public health practice more commonly found in administrative regulations or public health policies. Rather, by adopting a flexible approach, the Act's provisions can be tailored to any existing governmental public

health department or agency.

Many states (e.g., AK, NC) have already or are planning to (e.g., MT, OR) introduce new legislative bills based on the subject matter of the Turning Point Act. Other states are currently comparing the Act's provisions to their existing laws to determine potential gaps. These activities coincide with the Collaborative's intent in creating the Act to promote the assessment of public health laws, without mandating it. These voluntary efforts are the essence of public health law reform in the 21st century. They are motivated by the idea that improving public health law leads to better public health outcomes.

ANTHRAX VACCINATIONS: DOE V. RUMSFELD

JULIE S. MAIR

Six anonymous active duty and selected National Guardsmen and civilian contract employees of the Department of Defense, who have submitted or have been ordered to submit to anthrax vaccinations without their consent, filed suit on March 18, 2003, against the Secretary of Defense, the Secretary of Health and Human Services, and the Commissioner of the Food and Drug Administration (FDA). They claimed that Anthrax Vaccine Adsorbed (AVA) is an experimental drug unlicensed for inhalation anthrax. *Doe v. Rumsfeld*, 297 F.Supp.2d 119 (D.D.C. 2003). Granting a Motion for a Preliminary Injunction of the mandatory vaccina-

tion program, the Honorable Emmet G. Sullivan stated that "AVA is an investigational drug . . . being used for an unapproved purpose. . . . Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs."

Eight days later, on December 30, 2003, the FDA issued a controversial Final Rule and Order (18 years after the FDA published the proposed rule) stating that the vaccine was safe and effective for such use: "the efficacy analysis [of the vac-

cine] includes all cases of anthrax disease regardless of the route of exposure or manifestation of disease." Based on the FDA's Rule, the government immediately filed an emergency motion asking Judge Sullivan to vacate the injunction. On January 7, 2004, Judge Sullivan lifted the preliminary injunction because the principle reason for the injunction had been addressed by the FDA, but noted that "the timing of the issuance of the rule is arguably highly suspicious . . ." The case continues with respect to the six plaintiffs.

GLOBAL HEALTH GOVERNANCE IN THE WAKE OF SARS

SCOTT BURRIS

On March 24-25, Temple Law School and the Center sponsored a two day meeting of experts to discuss the future of global health governance in the wake of SARS. The meeting was intended to bring together people from fields that do not necessarily overlap for a high-level interchange organized around

a set of new papers. Among the presenters, whose papers will be published in the Fall issue of the Temple Law Review, were epidemiologist Ruotao Wang of the Chinese CDC; Center faculty Scott Burris, David Fidler, Larry Gostin, and Jason Sapsin; political scientist Susan Sell of George Washington University;

international law expert Obi Aginam of Carlton University; and Sofia Gruskin of the Francois-Xavier Bagnoud Center for Health and Human Rights at Harvard.

"The Turning Point Act presents the most comprehensive series of model provisions of state public health law ever produced in the United States."

FACULTY PUBLICATIONS

Center Publications

Symposium, *Emerging Issues in Population Health: National and Global Perspectives*, 31 J.L. Med. & Ethics 473 (Lawrence O. Gostin ed., 2003).

Lawrence O. Gostin

LAWRENCE O. GOSTIN, THE AIDS PANDEMIC: COMPLACENCY, INJUSTICE, AND UNFULFILLED EXPECTATIONS (2004).

THE HUMAN RIGHTS OF PERSONS WITH INTELLECTUAL DISABILITIES: DIFFERENT BUT EQUAL (Lawrence O. Gostin et al. eds., 2003).

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James G. Hodge, Jr.

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breaks, in Planning for Bioterrorism: Individual and Community Responses (Robert J. Ursano et al. eds., 2004).

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Scott Burris, Kim M. Blankenship, Martin Donoghoe, Susan Sherman, **Jon S. Vernick**, Patricia Case, **Zita Lazzarini**, & Stephen Koester, *Addressing the "Risk Environment" for Injection Drug Users: The Mysterious Case of the Missing Cop*, 82 Milbank Q. 125 (2004).

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Jon S. Vernick, **Julie S. Mair**, **Stephen P. Teret**, **Jason W. Sapsin**, *Role of Litigation in Preventing Product-Related Injuries*, 25 Epidemiology Rev. 90 (2003).

Jon S. Vernick et al., *Technologies to Detect Concealed Weapons: Fourth Amendment Limits on a New Public Health and Law Enforcement Tool*, 31 J.L. Med. & Ethics 567 (2003).

Zita Lazzarini

Zita Lazzarini et al., *Criminal Law*

and Public Health, in Law in Public Health Practice (Richard A. Goodman et al. eds., 2003).

Richard A. Goodman, Judith W. Munson, Kim Dammers, Zita Lazzarini, and John P. Barkley, *Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations*, 31 J.L. Med. & Ethics 684 (2003).

Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil*, 6 Yale Hum. Rts. & Dev. L. J. 103 (2003).

Zita Lazzarini & Robert Klitzman, *HIV and the Law: Integrating Law, Policy, and Social Epidemiology*, 30 J.L. Med. & Ethics 533 (2002).

David P. Fidler

DAVID FIDLER, SARS, GOVERNANCE, AND THE GLOBALIZATION OF DISEASE (2004).

David Fidler, *Germs, Norms, and Power: Global Health's Political Revolution*, J. L. Soc. Just. & Global Dev., (forthcoming 2004) <<http://elj.warwick.ac.uk/global>>.

David Fidler, *Fighting the Axis of Illness: HIV/AIDS, Human Rights, and U.S. Foreign Policy*, 17 Harv. Hum. Rts. J. (forthcoming 2004).

David Fidler, *Caught Between Paradise and Power: Public Health, Pathogenic Threats, and the Axis of Illness*, 35 McGeorge L. Rev. (2003) (forthcoming).

David Fidler, *SARS: Political Pathology of the First Post-Westphalian Pathogen*, 31 J.L. Med. & Ethics 485 (2003).

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Perspective on the Application of Human Rights Principles to Mental Health, 63 Md. L. Rev. 20 (2004).

Julie S. Mair

Michael Mair & Julie S. Mair, *A Complementary Approach to Bioterrorism Prevention*, 10 Nonproliferation Rev. 114 (2003).

Julie S. Mair, Shannon Frattaroli, and **Stephen P. Teret**, *New Hope for Victims of Prison Sexual Assault*, 31 J.L. Med. & Ethics 602 (2003).

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Julie S. Mair & Michael Mair, *Vaccine Liability in the Era of Bioterrorism*, 1 Biosecurity and Bioterrorism: Biodefense Strategy, Prac. & Sci. 169 (2003) <<http://www.biosecurityjournal.com>>.

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Jason W. Sapsin, Theresa M. Thompson, **Lesley Stone**, and Katherine E. DeLand, *International Trade, Law, and Public Health Advocacy*, 31 J.L. Med. & Ethics 546 (2003).

Lesley Stone

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Wendy Collins Perdue, Lesley A. Stone, and **Lawrence O. Gostin**, *The Built Environment and Its Relationship to the Public's Health: The Legal Framework*, 93 Am. J. Pub. Health 1390 (2003).

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CENTER ANNOUNCEMENTS

The Center is pleased to announce the addition of two new scholars to its Senior Faculty: **Zita Lazzarini**, Assistant Professor and Director, Division of Medical Humanities, Health Law, and Ethics, University of Connecticut School of Medicine; and **David Fidler**, Professor of Law, Indiana University School of Law.

The Center is serving as a collaborating organization for the upcoming CDC/ASLME conference on public health law from June 14-16, 2004 in Atlanta, GA. Center faculty will participate in several sessions, including a pre-conference legal preparedness workshop, a short course on legal preparedness for terrorism, and multiple concurrent sessions (subjects including commercial speech, model public health laws, litigation, and comparative quarantine laws). For more information, see www.aslme.org/conferences.

Center Director **Lawrence O. Gostin** was recently named to the *Homeland Security 100*, a listing of the top hundred officials/experts in homeland security and bioterrorism, by the National Journal.

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Health Through Law

LEGAL PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES: EMERGING PROJECTS

JAMES G. HODGE, JR.

Since its inception, the Center has worked closely with the public health community to address legal issues underlying public health emergency preparedness. Among our many activities, Center faculty drafted the Model State Emergency Health Powers Act (MSEHPA) in the Fall of 2001. A year later, we hosted a bioterrorism legal preparedness workshop. The MSEHPA and proceedings of our workshop are available at www.publichealthlaw.net.

Current Center projects continue these efforts. Together with colleagues at the CDC's Public Health Law Program, the Association of State and Territorial Health Officers (ASTHO), and the National Association of City and County Health Officials (NACCHO), Center faculty are addressing three major legal preparedness topics, summarized below.

Topic 1. *Interjurisdictional coordination between federal, state, and local governments on public health emergency preparedness.* Some of the most important and difficult legal issues in public health emergency preparedness concern how various levels of government (local, state, tribal, federal) coordinate prevention efforts, resources, and responses across boundaries. Coordination among gov-

ernments and their private sector partners is complicated by differences in law, policies, economics, and trade. To assist public health lawyers, practitioners, and policymakers, the Center will prepare an authoritative assessment guide, or checklist, to guide focused review of these issues. This checklist will provide a working tool for various actors at each level of government to examine potential legal issues that arise. Users can then apply their own legal analysis and findings regarding these issues on a jurisdiction-specific basis.

Topic 2. *Local government public health emergency preparedness and response issues.* "Local public health legal preparedness" refers to those legal powers and authorities local governments need to respond effectively to bioterrorism, infectious disease outbreaks, and other public health emergencies. These powers of local governments (e.g., counties, boroughs, cities, special districts) may be similar across states or within them, but significant diversity among these governments complicates the development of a model approach. The Center is producing a checklist that local governments can use to assess their legal preparedness for public health emergencies. This

checklist will adopt a multi-sectoral approach, assessing the sorts of authority at the local level involving public health agencies and their public and private sector partners.

Topic 3. *Legal liability issues concerning public health emergencies.* Liability issues for public and private sector agencies and their workers/volunteers concerning public health emergency responses are profound. Public health practitioners seek guidance and clarity in their examination of various legal theories or angles by which liability may derive. We are developing a self-assessment tool that addresses various liability theories of state and local governmental public health agencies and their officials, workers, and volunteers.

These and other issues will be discussed at the Center's co-sponsored legal preparedness workshop at the CDC's upcoming public health law conference on Monday, June 14, 2004.

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