



CENTER INSIGHTS

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CENTER FILES AMICUS BRIEF ON BEHALF OF SICK FLORIDA SMOKERS

STEPHEN P. TERET

At the close of a two-year trial of a Florida class action brought on behalf of all sick Floridian smokers or their survivors against the tobacco industry, a jury awarded the plaintiffs \$145 billion in punitive damages. On appeal, the same Florida appellate court that had certified the class in 1996 reversed itself and decertified the class, barring the imposition of punitive damages. (*Liggett Group, Inc. v. Engle*, 853 So.2d 434 (Fla. Dist. Ct. App. 2003).) The case has been appealed to the Supreme Court of Florida, and because of its enormous potential to affect one of the most serious public health issues worldwide, The Center for Law and the Public's Health chose to file an amici curiae brief, written by Center faculty Stephen Teret and Jon Vernick.

We are very pleased that we had the opportunity to write and submit the brief on behalf of the leading public health and medical organizations of the nation. The amici that signed on to the brief are: the American Public Health Association; the American Medical Association; the American Academy of Pediatrics; the American Heart Association; the American Lung Association; the American Legacy Foundation; and the Roswell Park Cancer Institute.

The brief, which has been accepted by the Supreme Court

of Florida, argues principally that class action litigation is an appropriate and necessary tool for addressing the epidemic of tobacco-related illness. After reviewing the epidemiologic data that demonstrate the continuing severity of this country's tobacco-related morbidity and mortality problems, the brief describes why class actions are needed to confront the health issues caused by the manufacture and sale of cigarettes. "A class action differs from multiple lawsuits in much the same way that public health differs from medicine," the brief asserts. "The difference is not only in the quantity of individuals involved, but also in the quality and method of problem solving."

To date, lawsuits brought by individual plaintiffs or their families have not been successful in altering the behaviors of tobacco companies to substantially reduce the disease-causing aspects of their products. The disparity between the assets available to an individual plaintiff for investment in the litigation process and those held by the tobacco companies has resulted in unsuccessful lawsuits and the reluctance of plaintiffs' attorneys to consider such lawsuits. Class action, however, evens the playing field by aggregating victims, and allows a trial court to consider the effects of the

defendants' conduct on the public's health, as well as the societal burden caused by the defendants' conduct.

The brief also argues that litigation has long been recognized as a legitimate tool for protecting the public's health. In response to the tobacco companies' argument that the imposition of punitive damages is inappropriate, the brief states that "The tobacco defendants have, for many years, reaped substantial profits from the creation and sale of an addictive, lethal product, and the public has paid for the product not only with money but also with millions of lives lost. The defendants continue to reap profits at the cost of lives. It is a quintessential role of tort law and the judiciary to address this wrong by the imposition of penalties that are severe enough to change the behavior of the wrongdoers and thereby prevent the substantial future harm that will otherwise occur."

The case is scheduled for oral argument before the Supreme Court of Florida on November 3, 2004.

CENTER FUNDED BY HRSA TO ADVISE ON EMERGENCY SYSTEM FOR ADVANCED
REGISTRATION OF VOLUNTEER HEALTHCARE PERSONNEL (ESAR-VHP)

LANCE A. GABLE AND JAMES G. HODGE, JR.

The Center has recently embarked on an exciting new project in collaboration with the Health Resources and Services Administration (HRSA). HRSA is principally responsible for coordinating the development of a state-based Emergency System for Advanced Registration of

Volunteer Healthcare Personnel (ESAR-VHP). This national system will facilitate the creation of state and territorial volunteer healthcare personnel databases for use in public health crises and other emergency response situations.

The ESAR-VHP initiative is a direct response to problems with the emergency preparedness infrastructure revealed by the attacks of September 11, 2001,

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REMODELING THE INTERNATIONAL HEALTH REGULATIONS
LESLEY STONE

WHO is currently undertaking to revise the International Health Regulations (IHR), the primary global agreement regarding the control of infectious disease. The IHR have not been substantially revised since 1969, and global events, including SARS, have eclipsed the usefulness of the current version.

The draft regulations improve upon their current counterparts in important ways. The current regulations only require that nations report three diseases (cholera, plague, and yellow fever). This leaves the world without a formal mechanism for dealing with emerging and reemerging diseases. In addition, the tools outlined in the current IHR for dealing with health emergencies are inflexible, leaving potential vulnerabilities.

The new regulations expand the province of the IHR from three diseases

to all "public health emergencies of international concern." The regulations contain an algorithm by which countries will determine if they are required to notify WHO of a disease outbreak or other health threat. (Countries would consider if the event would cause serious health impacts, is unusual or unexpected, might spread internationally, or would necessitate international restrictions on trade or travel.) Once the event is reported to WHO, it may make temporary or standing recommendations tailored to controlling the specific disease or health threat.

Member countries of WHO have expressed concerns about the initial draft of the new regulations. Principally, there were concerns that the new regime would be inconsistent with the states' obligations under other international law regimes

such as those governing trade, the environment, and diplomatic relations.

The Center explored these tensions in a report it submitted to WHO in July 2004. In reconsidering the draft IHR, WHO concluded that the proposed regulations were largely in harmony with major multilateral treaties with changes required in a small number of areas to achieve concordance between the draft IHR and other multilateral regimes. WHO has submitted a revised draft of the IHR to its member states, which is available at www.who.int/gb/ghs. WHO will host intergovernmental negotiations on the revised draft in November 2004, with the hope being that the final draft can be submitted to the World Health Assembly for approval in May 2005.

"Participants left Philadelphia with a variety of approaches to advance the field of health law in China."

THE TEMPLE HEALTH LAW WORKSHOP
JASON SAPSIN

Temple University's Health Law Workshop, funded by USAID and directed by Professor Scott Burris (Temple University), Center Associate Director, and Jason Sapsin (Johns Hopkins), Center Scholar, was recently completed in July. The Workshop, held to develop the field of health law in China, brought Chinese legal scholars and government officers together with prominent U.S. health law academics. Over the course of the four-week program, participants attended 3-5 seminars per week and developed teaching curricula, research projects, and work plans for the 2004-2005 academic year. The Workshop culminated in a two-day visit to Washington, D.C. to meet attorneys, government officials, and interest groups actively involved in

health law and policy.

The Chinese scholars and attorneys represented China University of Political Science and Law, Sun Yatsen University, Jilin University, Tsinghua University, Zhejiang University, Sichuan University, Yunnan University, Peking University, the People's Congress of Shanghai, and the Ministry of Commerce of China.

American guest faculty presenting seminars represented the University of Michigan, Rutgers, University of North Carolina, Johns Hopkins University, Brooklyn Law School, Georgetown University, Wake Forest University, and Northeastern Law School. Topics included U.S. Health Law, Health Policy and Politics, Dis-

ability Law, HIV/AIDS and the Law, Public Health Law, Bioethics, Human Rights, and Injury Control.

Participants left Philadelphia with a variety of approaches to advance the field of health law in China. Several scholars will offer health law related courses in their home institutions. Other participants have programs to advance their research or legislative drafting projects. The group currently is organizing conferences on health law and related topics (the first to be held in December at Kunming and sponsored, in part, by Yunnan University) and preparing the seminal Chinese text on health law.

FACULTY PUBLICATIONS

Center Publications

Jon S. Vernick, Jason W. Sapsin, Stephen P. Teret & Julie S. Mair, *How Litigation Can Promote Product Safety*, J.L. MED. & ETHICS (forthcoming 2004).

Jason W. Sapsin, Lawrence O. Gostin, Jon S. Vernick, Scott Burris & Stephen P. Teret, *SARS and Legal Preparedness*, TEMP. L. REV. (forthcoming 2004).

Lawrence O. Gostin

Lawrence O. Gostin, et al., *The Future of the Public's Health: Vision, Values, and Strategies*, 23 HEALTH AFF. 96 (2004).

Lawrence O. Gostin, *International Infectious Disease Law: Revision of the World Health Organization's International Health Regulations*, 291 JAMA 2623 (2004).

Lawrence O. Gostin, et al., LAW, SCIENCE, AND MEDICINE (forthcoming 2005).

Lawrence O. Gostin, ed., *Comparative and International Health Law: A Tribute to Bernard Dickens*, J. L. MED. & ETHICS (forthcoming 2005).

Lawrence O. Gostin, *Pandemic Influenza: Public Health Preparedness for the Next Global Health Emergency*, J.L. MED. & ETHICS (forthcoming 2005).

James G. Hodge, Jr.

James G. Hodge, Jr., *Genetic Testing and Screening: The Public Health Context*, in ENCYCLOPEDIA OF BIOETHICS (Stephen G. Post, ed., 3rd ed., 2004).

James G. Hodge, Jr. & Gabriel B. Eber, *Tobacco Control Legislation: Tools For Public Health Improvement*, 32 J.L. MED. & ETHICS 516-523 (2004).

Dan Drociuk, James J. Gibson & James G. Hodge, Jr., *Health Information Privacy and Other Legal Perspectives Concerning Syndromic Surveillance*, 53 MORBIDITY & MORTALITY WKLY. REP. 221 (2004).

James G. Hodge, Jr., *Virginia Genetics Law and Policy: A White Paper for the Virginia Advisory Board*

on Legal/Ethical Issues in Genetics (April 30, 2004).

Brian Kamoie & James G. Hodge, Jr., *HIPAA's Implications For Public Health Policy and Practice*, 119 PUB. HEALTH REP. 216 (2004).

Lesley Stone

Lesley Stone & Lawrence O. Gostin, *Using Human Rights to Combat the HIV/AIDS Pandemic*, HUMAN RIGHTS (forthcoming 2004).

Jon S. Vernick

Daniel W. Webster, Jon S. Vernick, April M. Zeoli & Jennifer A. Manganello, *Association Between Youth-focused Firearm Laws and Youth Suicide*, 292 JAMA 594 (2004).

Jason Sapsin

Daniel A. Salmon, Jason W. Sapsin, Stephen Teret, et al., *Public Health and the Politics of School Immunization Requirements*, AM. J. PUB. HEALTH (forthcoming 2004).

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the anthrax exposure that same Fall, and subsequent emergency preparedness simulations. Most jurisdictions lack an effective and efficient system to pre-register volunteer healthcare personnel for emergencies. Furthermore, there is no nationally-accepted method for verifying healthcare provider credentials and qualifications.

Cognizant of these recognized dilemmas and with guidance from the Secretary of the Department of Health and Human Services, Congress enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). Pursuant to this act, HRSA is leading development of ESAR-VHP. The primary purpose of ESAR-VHP is to assist medical professionals in volunteering for emergencies and disasters by providing verifiable, up-to-date information regarding the volunteers' identity and licensing, credentialing, accreditation, and privileges at hospitals or other medical facilities.

HRSA convened a Focus Group in May 2004 to identify and assess ESAR-VHP

development and implementation issues. Three coordinated efforts to develop and implement the ESAR-VHP guidelines emanated from this meeting: (1) a project focused on guidelines, standards, and definitions development support; (2) a project to identify and discuss options for development and implementation issues for hospitals; and (3) the Center's project to identify and propose solutions for the legal and regulatory issues that underlie ESAR-VHP.

Over the next 2 years and with input from an expert Project Advisory Group, the Center will advise HRSA and its federal, state, and territorial partners on the legal and regulatory issues that relate to the development and implementation of ESAR-VHP. These issues include authority to declare public health or general states of emergency, civil and criminal liability, interjurisdictional concerns, workers' compensation, licensing/credentialing, and health information privacy. Beyond mere identification, we will suggest possible options and recommendations for resolving these legal issues through our national report due in December, 2004. As well, the Center will provide technical assistance to states and territories implementing their own systems

through the end of the project in 2006.

James G. Hodge, Jr. is the Principal Investigator of the project. **Lance A. Gable** is the Project Director. **Stephen P. Teret** and **Jon S. Vernick** are co-investigators and **George (P.J.) Wakefield** will serve as Project Administrator. For more information, please contact Lance A. Gable at (202) 662-9281 or gable1@law.georgetown.edu.

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CENTER ANNOUNCEMENTS

The *Center* is pleased to announce that **Lawrence O. Gostin**, J.D., LL.D. (Hon.), Director, has been named the John Carroll Research Professor at Georgetown University Law Center for 2004/2005.

The *Center* is also pleased to announce that **James G. Hodge, Jr.**, J.D., LL.M., Executive Director, has been promoted to Associate Professor at the Johns Hopkins Bloomberg School of Public Health.

The *Center* is pleased to announce that **Lesley Stone**, J.D., and **Lance A. Gable**, J.D., M.P.H., have been named Senior Fellows. **Mr. Gable** has also recently been named Project Director of the *Center's* ESAR-VHP Legal and Regulatory Issues and Solutions Project, sponsored by HRSA (see page 2 of this issue).

Lawrence O. Gostin has been appointed Chair of the Institute of Medicine's Committee on Genomics and Public Health in the 21st Century. He also chaired the workshop on October 7-8, 2004 where **James G. Hodge, Jr.** provided a conference summary. For more information see, <http://www.iom.edu/event.asp?id=21464>.

PANDEMIC INFLUENZA: PREPAREDNESS FOR THE NEXT GLOBAL HEALTH EMERGENCY LAWRENCE O. GOSTIN

Influenza pandemics have occurred roughly 2-3 times per century, causing untold suffering. There are three essential prerequisites for an influenza pandemic: the existence of a novel viral subtype in animals, viral replication causing disease in humans, and efficient human-to-human transmission. Since 1997, the first two prerequisites have been met on numerous occasions. During 2003/04, highly pathogenic influenza A (H5N1) outbreaks occurred among poultry in Asia. More than 200 million birds were culled or died; 31 of 43 infected humans also died.

There is now intense interest in influenza preparedness (especially given this year's vaccine shortages), with major planning undertaken by the World Health Organization (WHO) and Institute of Medicine (IOM).

Global Surveillance

Surveillance of novel infections in humans offers an early warning and provides an opportunity for a timely response. Despite its importance, many countries do not conduct effective and timely surveillance. Prompt notification of an infectious disease threat can affect a country's tourism, trade, and prestige. The current International Health Regulations (IHR) are weak, applying only to three diseases: cholera, plague, and yellow fever.

Vaccination: The Challenges of Reliable Production and Delivery

An influenza pandemic would necessitate "surge capacity" in the development and delivery of vac-

cines. Yet, the prospects appear dim. Private sector development of effective vaccines requires stable markets, venture capital, and economic incentives—none of which exist. What is urgently needed is an effective public/private partnership to stimulate vaccine production such as the establishment of a National Vaccine Authority.

Antiviral Therapy: The Challenges of Rationing a Scarce Public Good

When vaccination is unavailable, authorities may use the antiviral Tamiflu. Tamiflu, however, is costly, in short supply, and may be effective only if administered during the first two days following the onset of symptoms. Pandemic influenza would likely result in a paucity of antiviral medications, raising the hard problem of fair allocation of scarce resources. What ethical values should guide rationing decisions: private need (treatment of the sick); public need (prevention among vulnerable populations); maintenance of essential services ("first responders"); or political influence (priority for those with political connections)? Justice may require that therapeutic interventions be used to benefit the most people possible, irrespective of their power or influence. The global reality is that rich countries will have much less scarcity than poor countries. The ethical question then arises whether developed countries would be expected to forego some of their antiviral stockpiles for the sake of poorer countries.

Travel and Border Controls

International or national health agencies may issue travel adviso-

ries or establish border restrictions instinctively, to protect their national borders. Travelers legitimately claim the right to know health risks, but restrictions significantly affect tourism and trade. Consequently, travel advisories can be politically charged, as were WHO advisories concerning SARS. When faced with a hard tradeoff between maximization of health or of trade, which should prevail and why? Arguably, health should take precedence over trade because of the fundamental value of human functioning and life itself.

The Public Health Paradox

There is no way to avoid the dilemmas posed by acting without full scientific knowledge. Failure to move aggressively in the early stages of pandemic influenza can have catastrophic consequences. Actions that prove to have been unnecessary will be viewed as draconian and based on hysteria. The only safeguard is the adoption of ethical values in formulating and implementing public health decisions. Public health policy will reflect the manner in which humane societies both implicitly and explicitly balance the common good with respect for personal rights.

Professor Gostin was a member of WHO's consultation on influenza preparedness and is working with WHO on the IHR revision. He also participated in the IOM Workshop on preparing for the next pandemic. The views in this article do not necessarily reflect those of WHO or IOM.

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