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IN THIS ISSUE:

FOCUS ON . . .

Public Health Preparedness 1

The Center for Health &
Homeland Security at the
University of Maryland,
Baltimore 6

Alum Working on Emergency
Preparedness 10

LAW & HEALTH CARE PROGRAM NEWS

In the Clinic 11

DHMH Secretary Meets with
Students & Faculty 12

Creating Ties with the Medical
School—Personally and
Professionally 12

L&HCP Sponsors Conference
on the Ethics of Health
Care Reform 13

Student Health Law Organization
Hosts “Speed Networking”
Event 13

Health Law Students & Faculty
Travel to China 14

L&HCP Alum and Adjunct
Professor Takes Lead Role in
Crafting Stark III Regs 16

L&HCP FACULTY NOTES 18

FROM THE DIRECTOR . . .

In this issue, we focus on public health emergency preparedness and the body of law that supports this emerging field. Since 2002, the Law & Health Care Program has collaborated with the Center for Health and Homeland Security. The Center has been at the front line of developing policies and programs relating to public health preparedness and has provided Law & Health Care Program students and graduates with the opportunity to make substantial contributions in the field. We also highlight the work of two of our alums, our trip to China over spring break, and recent conferences and events. We hope you enjoy the issue and have a great summer!

Diane Hoffmann, JD, MS

PUBLIC HEALTH PREPAREDNESS

The United States experienced natural and man-made disasters prior to the terrorist attacks of September 11, 2001 and Hurricane Katrina, but the one-two punch of those devastating events within four years of each other focused the nation as never before on our ability to prepare for, and respond to, such disasters. In the last seven years, there has been unprecedented executive branch shuffling, legislative activity at all levels of government, and vast public expenditure to ensure that we are prepared to meet the challenges of the next disaster. These efforts have raised innumerable legal questions from the fundamental—*who’s in charge during a crisis*—to the practical—*who gets the last dose of the vaccine?*—and has created a body of law built around answering these questions. This body of law, which is generally called the law of public health legal preparedness, is primarily concerned with answering the complicated legal issues that are raised when multiple systems are disrupted and making sure that those issues are resolved and understood prior to a disaster. These efforts are designed to ensure that, during a disaster, the legal system supports, rather than hinders, relief efforts.

The concept of emergency preparedness encompasses a myriad of activities—mass transit planning, evacuation planning, information technology security, communications planning, continuity of operations planning, critical

infrastructure protection, and protection of the public’s health during and following a crisis. In this issue of our newsletter we focus on this latter component of emergency preparedness—public health preparedness—and its associated legal issues. We also highlight the work of the Center for Health and Homeland Security (CHHS) at University of Maryland Law School (see article on page 6). Since its inception in 2002, CHHS has been at the forefront of preparing federal, state and local officials to meet the structural and legal challenges of emergency preparedness.

Public Health Preparedness

The term “public health preparedness” was first used in the late 1990s in the context of new and emerging infectious diseases and the threat of bioterrorism.¹ It has been defined as the readiness of a public health system (of a community, a state, a nation, or the world community) to respond to specified health threats.² It has also been defined as a goal—the attainment by the public health system of defined benchmarks of response to conventional dangers and to emerging threats of infectious disease outbreak, terrorism, or natural disaster.³

Public health disaster planning is extremely challenging for many reasons, including the variability of scenarios that threaten the public’s health. Some disasters are primarily public health emergen-

Cont. on page 2

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Public Health Preparedness

Cont. from p. 1

cies, such as an infectious disease outbreak or release of a biological agent. Other disasters, such as hurricanes, affect society as a whole with varying impacts on the public's health. Prior to Hurricane Katrina, individuals working in the area of public health emergency preparedness thought mainly in terms of bioterrorism, but the SARS virus and Hurricane Katrina broadened that perspective to encompass an "all-hazards" (both natural and man-made disasters) approach to planning. While different types of disasters create different health-related issues, commentators have noted that planning for all-hazards revolves around the common themes of meeting the health needs of populations rather than individuals and coordinating responses among government entities.⁴

Even prior to 9/11, work was underway to improve public health preparedness in the United States. In 2000, Congress passed the Public Health Threats and Emergencies Act authorizing a national program to assess public health infrastructure state by state. After 9/11, Congress enacted the Public Health Security and Bioterrorism Response Act of 2001 which authorized a CDC grant program to assist states and the cities of New York, Chicago, and Los Angeles to strengthen their capacity to prepare for and respond to massive public health threats. Since 2001, the program, called the Public Health Emergency Preparedness Cooperative Agreement, has given more than \$5 billion to public health departments through grant-funded cooperative agreements. As part of the program, CDC established six public health preparedness activities upon which grantees are evaluated: prevention, detection and reporting, investigation, control, recovery, and improvement.⁵

Public Health Legal Preparedness

An essential element of public health preparedness that has been the subject of intense scrutiny and activity since 9/11 is public health *legal* preparedness. The concept has been defined as attainment by a public health system of the legal benchmarks essential to preparedness, or the contribution of legal tools to assuring the conditions in which people can be healthy.⁶

While efforts were underway to improve the nation's public health legal preparedness prior to 9/11, they sped up dramatically after that date. Concrete steps toward public health legal preparedness have been taken as the result of several independent initiatives.⁷ One initiative was the creation of the Turning Point Public Health Statute Modernization National Collaborative, an initiative of the Robert Wood Johnson Foundation and the W.K. Kellogg Foundation.⁸ The Collaborative authored the Turning Point Model State Public Health Act, which offered a menu of provisions for state and local officials to assess their existing statutory and regulatory public health laws. A variety of legislative activities have taken place in several states as a result of the Act. Between January 2003 and June 2005, 32 states introduced over 75 bills or resolutions on public health subjects.⁹

Another effort designed to improve public health legal preparedness was the establishment of the Public Health Law Program at the Centers for Disease Control (CDC).¹⁰ In June 2007, CDC and eighteen multidisciplinary partners convened the first National Summit on Public Health Legal Preparedness (CDC Summit). The purpose of the meeting was to provide a structured opportunity for leaders in the field to assess the current state of legal preparedness, and to develop a national action agenda supportive of law-based strategies to address potential public health emergencies.

Core Elements of Public Health Legal Preparedness

The national action agenda developed at the CDC Summit was framed around the four core elements of public health legal preparedness: 1) legal authorities based in science and/or on contemporary principles of jurisprudence; 2) competency in applying law to public health goals; 3) cross-sector and cross-jurisdiction coordination of law-based interventions; and 4) information on legal preparedness best practices.¹¹

1. Legal Authority

Underpinning all of the core elements of legal preparedness is the fundamental issue of power—and therefore responsibility—of and among federal, state, and local agencies in a disaster. The powers and responsibilities of the various agencies that play a role in public health are rooted in law. Any attempt to coordinate an emergency response first requires an understanding of the legal foundations and authorities that support the various players in an emergency. CDC Summit participants agreed that while some new public health laws might be necessary to enhance emergency preparedness, a better understanding and closer scrutiny of existing law and its use by practitioners is more important.¹² Summit participants also noted that public health practitioners and their counsel are often uncomfortable making use of existing legal authorities even if they are familiar with those laws.¹³ The reasons for this may include lack of familiarity with the law; confusion over perceived and actual conflicting authorities; distress over conflicting ethical considerations; and perceived and real political considerations.¹⁴ Summit participants recommended an ongoing effort on the part of all levels of government to ensure that public health laws are both widely understood and able to be employed correctly in an emergency.¹⁵

2. Competency

Ensuring the public health workforce and their attorneys are familiar with and able to use legal authorities in an emergency situation dovetails with the second core element of public health legal preparedness—public health legal competency.



Following the release of the Institute of Medicine's influential report, *The Future of Public Health*, 20 years ago, public health professionals and academics developed a set of core competencies to help strengthen the public health workforce, as well as their designated attorneys and policy-makers. These established competencies include legal competencies that are not tailored to emergency legal preparedness, but provide a base for competencies in emergency response.¹⁶ Since the development of the core competencies, there have been efforts to specify competencies necessary for public health legal preparedness and response. These include:

- Interpreting public health law before, during, and after public health emergencies;
- Applying emergency law and provisions in response to a declared emergency;
- Identifying legal issues requiring potential reform or mediation;
- Assessing the consequences of legal action or inaction; and

- Integrating legal decisions within the larger public health response.¹⁷

One rather unique feature of the push to increase legal competency in the public health workforce is the recognition that public health officials need to possess sufficient legal knowledge to accomplish specific legal tasks in an emergency without having to depend on an attorney. The primary legal activities associated with a public health response to an emergency (and the activities that a public health official should be able to understand and navigate) have been identified as:

1. Conducting searches of private premises;
2. Seizing or closing private property;
3. Providing and directing treatment or screening;
4. Implementing quarantine, isolation, or other restrictions of movement;
5. Issuing or revoking licenses or permits; and
6. Protecting confidentiality in the collection, maintenance and release of information.¹⁸

While ideally an attorney would assist in initiating and overseeing these tasks, the activities in this list are so critical to emergency response that public health officials should be able to undertake them immediately, even when the assistance of an attorney is not readily available.

3. Coordination

The coordination of public health and other authorities in an emergency requires effective coordination of legal tools and law-based strategies across local, state, tribal, and federal jurisdictions. Of all the challenges in public health preparedness, coordination may be the most difficult. As noted by one commentator, government

jurisdictions can be viewed *vertically*, in that response efforts may entail coordination of the application of laws across multiple levels, including local, state, tribal and federal governments. Jurisdictions can also be viewed *horizontally*, in that response efforts to public health emergencies may involve coordinating activities across numerous and diverse sectors, such as public health, public and private health care, emergency management, education, law enforcement, the judiciary, and the military.¹⁹ Further complicating cross-jurisdictional and cross-sectional coordination in an emergency is that coordination efforts will be different depending on the acute health threat at hand and its geographical and geopolitical context.

Much has been written regarding coordination in an emergency, especially following the disastrous and muddled response of all three levels of government to Hurricane Katrina. Based on the traditional reserved powers of the states in our Federalist system of government, states retain broad powers to manage all issues relating to disaster preparation and response. Federal authority for emergency response is generally limited to situations in which states request assistance.

In order for federal resources to be made available to states in an emergency, the President must declare an emergency under the Stafford Act, the statutory authority for most federal disaster response activities, especially as they pertain to the Federal Emergency Management Agency (FEMA) and its programs.²⁰ The process by which emergencies are declared and managed under the Stafford Act was overhauled after 9/11. Under the direction of Congress through the Homeland Security Act²¹ and of the President through Homeland Security Presidential Directive 5, the Department of Homeland Security (DHS)

promulgated a National Response Plan (NRP) in December 2004.²² Under the NRP, if the President declares an emergency under the Stafford Act, it is an “Incident of National Significance” and calls into play the broad federal oversight mandated by the plan. Under the NRP, the federal government can intervene in state disaster relief efforts without a request for assistance in certain circumstances.²³

In terms of health care, the NRP provides for federally directed medical assistance to supplement state and local resources in response to an Incident of National Significance and allows for the deployment of the federal National Disaster Medical System (NDMS), a coordinated effort by the Department of Health and Human Services, DHS, the Department of Veterans Affairs,

on interstate commerce,” and believe that the federal role in public health emergencies should be more proactive than currently structured.²⁶

Recognizing that conflicts over power and responsibility created incredible logistical and response problems following 9/11 and, to an even greater degree, after Hurricane Katrina, the states have taken action to clarify their powers in a public health emergency with a call to expand states’ emergency response powers. In 2000, officials at the CDC, public health experts, attorneys general, governors, and others began drafting a Model State Emergency Health Powers Act. This effort was expedited after 9/11 and the first draft was completed in October 2001. The purpose of the Act, according to the drafters, was to update public

The coordination of public health and other authorities in an emergency requires effective coordination of legal tools and law-based strategies across local, state, tribal, and federal jurisdictions. Of all the challenges in public health preparedness, coordination may be the most difficult.

and the Department of Defense.²⁴ The NDMS works in collaboration with the states and other appropriate public and private entities in providing medical response, patient evacuation, and medical care to victims and responders of a public health emergency.

There is ongoing controversy about the roles that the federal government and the states should take in a disaster and when federal assistance should be “triggered.” Legal commentators have noted that while states traditionally retain power to regulate health, the effect of public health on economic activity should allow the federal government to regulate public health via the Commerce Clause of the Constitution.²⁵ They point to Hurricane Katrina as “a prime example of the impact of a catastrophic public health emergency

health laws to reflect contemporary understandings of infectious disease and the law.²⁷ The Act clarifies a state’s power to act in five different areas—quarantine, surveillance, property management, protection of persons, and public information and communication. Under the Act, a governor can take exclusive and substantial control over public health, transportation, business, and law enforcement within a state during a catastrophic public health emergency, including the ability to compel quarantine, isolation, force medical treatment and vaccinations, as well as seizing whatever items are needed to respond to the emergency.

Although the Model Act has been somewhat controversial—primarily because of concerns regarding the scope of state executive power and

encroachments on civil liberties—as of October 2006, 44 states and the District of Columbia had passed laws incorporating at least some of the Model Act provisions. The Act has also been criticized for all but ignoring the federal role in a public health emergency notwithstanding the vast health-care related resources that can be deployed under the NRP.

The issue of power and responsibility in a disaster is critically important in public health emergency planning because of the overlapping and complex interplay of federal and state law in the regulation of health care in this country. One area of cross-jurisdictional and cross-sectoral coordination that has been singled out as requiring increased focus is coordination between public health authorities and health care providers in emergency preparedness and response efforts. For example, coordination on this front will require hospital attorneys, who are not directly involved in public health or preparedness activities on a daily basis, to be familiar with the relevant laws relating to emergency response in their jurisdictions and with the authority of public health agencies to impinge upon providers' interests, legal duties, responsibilities, and protected rights during emergencies.²⁸

Participants at the CDC Summit recognized that public health officials and health care providers work under different legal frameworks, which may make coordination difficult during an emergency.²⁹ As an example, they noted that health care providers, whether public or private, may be subject to regulatory issues that do not affect all public agencies, such as state licensure requirements that restrict services offered by health care providers and the number of persons that can be treated. These requirements may complicate or limit response during emergencies when healthcare organizations and individual providers are expected or

required to deliver care in off-site, non-medical facilities or other settings. Summit participants developed a list of recommendations to address the issue of conflicting legal frameworks, including recommending that jurisdictions provide liability protections to health care providers and organizations delivering care in emergencies.³⁰

4. Information

The CDC and others are developing materials to ensure that all those who respond to public health emergencies have access to the information necessary to develop the legal competencies required to prepare for and respond to a public health emergency. This constitutes the fourth core element of public health legal preparedness—information. In the context of public health legal preparedness, information



means timely, accurate, and accessible information, including case law, legal advice and opinions, and other information that can be used in shaping and applying public health law, specifically in the context of public health emergencies.³¹ CDC Summit participants divided public health law-related information into the information necessary for the three phases of public health emergencies – pre-event planning, event response and post-event recovery.³² The need for law-related information varies across these phases and according to the roles and responsibilities of the actors in an emergency.

Suggestions for improving information in all these phases include developing and disseminating jurisdiction-specific public health emergency legal preparedness information, improving the means to communicate such information to the public health workforce, and conducting applied research and development in legal preparedness.³³

—Virginia Rowthorn, JD

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Cont. on page 9

THE CENTER FOR HEALTH AND HOMELAND SECURITY AT THE UNIVERSITY OF MARYLAND, BALTIMORE

Shortly after the September 11, 2001 terrorist attacks, University of Maryland Baltimore President David J. Ramsay created the University of Maryland Center for Health and Homeland Security (CHHS) to develop, coordinate, and expand upon the University's extensive scientific research, health programs, policy development, training, legal analysis and consulting on counterterrorism and emerging public health response issues. CHHS, which will celebrate its 6th anniversary in May, is housed at the University of Maryland School of Law and directed by law school professor Michael Greenberger, a former high-ranking U.S. Department of Justice official.

CHHS staff members work with governmental units within the National Capital Region, the City of Baltimore and surrounding localities, the State of Maryland, and the federal government to address a broad range of problems and policies pertaining to homeland security. Many of the Center's programs and initiatives involve public health preparedness, which requires CHHS staff to tackle the complex and overlapping federal and state laws that govern public health matters. This overlap between health law and emergency preparedness has been a rich source of collaboration between the Law School's Law & Health Care Program and CHHS, and has provided the opportunity for joint conferences, externship opportunities for health law students, and employment opportunities for recent health law graduates.

CHHS began its work in 2002 with three staff members. Recently, the center hired its 50th staffer. Twenty-eight members of the CHHS staff are School of Law graduates. Other staff members are law school graduates from University of Virginia, University of Penn-

sylvania, Emory, Tulane, Howard, American, Case Western Reserve, and University of Baltimore law schools.

Director Greenberger recently joked that, with so many CHHS staffers



*CHHS Director and School of Law
Professor Michael Greenberger*

working in emergency planning at various levels of government across the region, he has been accused of running a "shadow government." The accusation was meant as a compliment and Greenberger takes it that way. CHHS staff members work side-by-side with the nation's top emergency planning officials on the development of a wide range of plans, strategies, and policies. As an outgrowth of the Center's work in all areas of emergency preparedness and response, CHHS has become a national leader in the law of emergency response—much of that in the area of public health. The Center performs this work not only through contracts with city, state and national government agencies, but in the public health arena through contracts with hospitals. In this article, we highlight a number of the Center's projects in the area of

public health preparedness.

CHHS's Public Health Projects

COOP Training and Planning

According to Greenberger, helping government officials at all levels plan for continuity of operations (COOP) in the event of a disaster is CHHS's "signature issue." These COOP plans ensure to the fullest extent possible that essential government functions will not be disabled during man-made or natural disasters, and that critical services and communication links will be maintained. COOP planning involves the creation of contingency plans that can be triggered during an emergency to ensure critical communication and computer systems remain operational; vital records and documents are preserved; personnel and equipment are moved to pre-positioned alternative locations; and an emergency work force is deployed to restart essential government services. Ideally, COOP plans should ensure that an agency or organization is operational at all alternate sites within twelve hours after an emergency has disabled its primary work location.

CHHS began working with the Maryland Emergency Management Agency (MEMA) in June 2003 to develop a manual for Maryland state agencies to use in developing their COOP plans. The first version of the COOP Manual was published in January 2004, and an updated version was published in July 2005. Based on the expertise developed during this process in Maryland, in October 2005, CHHS and MEMA were awarded \$1.484 million from the U.S. Department of Homeland Security (DHS) to run a Federal Continuity of Operations Training Program. In 2007, CHHS received an additional \$650,000 grant from DHS and FEMA for the continuation of the same activities. As part of the grant, CHHS staff developed a

course entitled, “Preparing the States: Implementing Continuity of Operations Planning,” that is designed to train emergency preparedness officials throughout the nation to develop COOP plans.

Specifically in the area of public health preparedness, CHHS staff members are engaged in COOP planning for the Baltimore City Health Department. This is an especially challenging COOP project because a health depart-



A CHHS staff attorney evaluates a simulated hurricane exercise in Baltimore City

ment must take the lead in responding to a disaster while simultaneously maintaining and protecting its basic non-emergency-related functions. According to Michael Stallings '07, a CHHS employee working in the Baltimore City Health Department, the two greatest challenges posed by COOP planning for a health department are personnel and facilities issues. If facilities are debilitated or contaminated during a disaster, alternative sites must be found. This is more challenging in the case of health facilities than office buildings because of the critical services provided in health facilities and the medical equipment inside those buildings. The COOP plan for the Baltimore City Health Department will be

tested during a discussion-based “table top” exercise later this year.

CHHS staffers are also preparing a COOP plan for the University of Maryland, Baltimore (UMB) campus. COOP planning for UMB—home to the Schools of Law, Medicine, Social Work, Nursing, Pharmacy, and Dentistry—involves some unique health-related issues, including maintaining functioning laboratories and preserving medical research. The campus

houses a Biosafety Level 3 laboratory, and although the lab is certified with plans in place to protect the public from potentially hazardous materials in the case of an emergency, the campus COOP plan will make sure that the existing emergency procedures are integrated with COOP planning for the rest of the campus. COOP planning for research laboratories also in-

volves protection of human and animal research subjects and protection of research. Megan Timmins '07, one of the CHHS employees working on the campus COOP plan, noted that a critical issue in developing the plan has been understanding responsibilities and duties between the medical school and the hospital in an emergency and the role of medical students, who play a significant role in the hospital's functions.

The Middle-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (MARCE)

CHHS Director Michael Greenberger has a long-standing collaborative

relationship with the Middle-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (MARCE)—a consortium of fourteen universities, seven government agencies, and ten corporate partners who are working together on research designed to enable a rapid government response to bioterrorism and emerging infectious diseases. Consortium members are studying vaccines and treatments for anthrax, West Nile virus, smallpox, and cryptosporidiosis, as well as needle-free vaccinations and new diagnostic tools, among other things. Much of MARCE's work is funded by grants from the National Institute of Allergy and Infectious Diseases (NIAID).

Myron Levine, MD, DTPH, Director of the Center for Vaccine Development at the University of Maryland School of Medicine, is the principal investigator for MARCE projects at UMB and a MARCE director. His work is primarily focused on developing vaccines against terrorist pathogens and pandemic flu. CHHS staff members have advised the Center for Vaccine Development on intellectual property and commercialization issues relating to vaccines and on other issues relating to reinvigorating the vaccine industry. Recently, Dr. Levine asked CHHS to work on a large-scale project relating to coordinating resources of first responders in the case of a public health emergency.

In February 2007, CHHS organized and hosted the MARCE-sponsored conference “Responding to Regional Catastrophic Public Health Events.” Its purpose was to provide a forum to address the readiness of the Middle Atlantic region to respond collaboratively to a multi-jurisdictional, multi-state public health catastrophe. According to Professor Greenberger, the event

was historic because it allowed the top medical biodefense researchers in the Middle Atlantic States to begin an important dialogue with first responder agencies within that region.

Medical Surge Planning

Serious public health emergencies challenge the ability of both public and private health care systems to care adequately for large numbers of patients and victims who may also have unusual or highly specialized medical needs. A surge plan is designed to provide a systematic approach to organizing and coordinating available health and medical resources so that health care providers can perform efficiently under the stress of a serious public health emergency. Maryland's Department of Health and Mental Hygiene (DHMH) asked CHHS to assist the State's Health and Medical Surge Technical Advisory Group develop and write the Maryland Health and Medical Surge Plan. The plan will identify the response plans and resources necessary to prepare adequately for medical surge; define health and medical priorities in the event of an emergency; identify the roles and responsibilities of hospitals and others in the health care community during an emergency; identify the roles, responsibilities, powers, and resources of local, state, and federal agencies during an emergency; and describe the chain of command and the communication systems to be used during an emergency.

Baltimore City Hospitals' Memorandum of Understanding

In 2005, the Baltimore City Health Department asked CHHS to develop a Memorandum of Understanding (MOU) between Baltimore City's eleven acute care hospitals to help them work together in the event of a bioterrorist attack or other public health catastrophe. The MOU, which was signed in 2007, is designed to

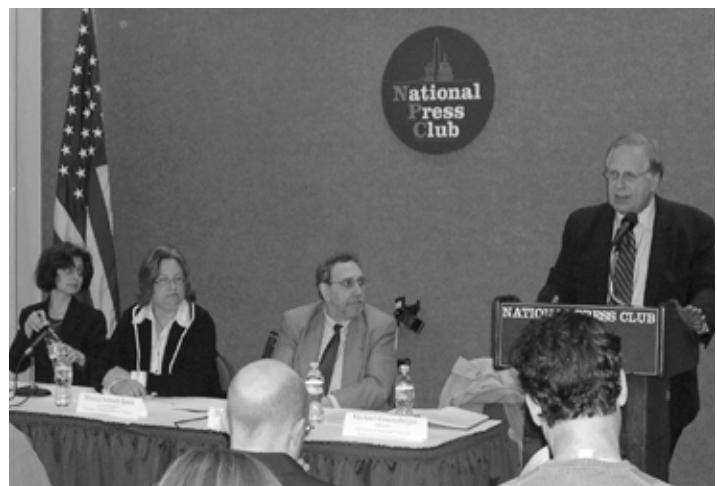
help hospitals coordinate activities and share supplies in various situations ranging from a spike in 911 calls relating to an apartment fire to a large scale disaster. The CEOs of these hospitals now meet once a month to discuss issues relating to the MOU and ensure continued coordination.

At-Risk Population Emergency Planning

Individuals who, for whatever reason, are unable to take the same measures to protect themselves as others at the time of an emergency are considered "at-risk" populations from an emergency preparedness perspective. This functional definition includes the poor, the isolated, the elderly, the disabled, children, the homeless, those without transportation, and non-English speakers. CHHS has been at the forefront of emergency planning for these populations. In November 2007, CHHS brought together approximately sixty researchers, practitioners, and advocates to share their knowledge and experiences at the first national conference on emergency preparedness for at-risk populations. Experts in disaster communication, transportation, and health care joined with those on the front lines of disaster response management to identify solutions to the challenge of disaster preparedness for these populations. One outcome of the conference was the "National Action Plan." The Plan is a report of the recommendations made at the conference and is based on twin principles agreed upon at the conference—collaboration across

different disciplines and sectors and engagement of vulnerable populations in the preparedness process.

Arienne Spaccarelli '07 is part of the Statewide Special Needs Exercise Committee working to test the quality of existing emergency plans for these populations. In June, the Maryland Department of Health and Mental Hygiene will hold a pandemic flu exercise, and Ms. Spaccarelli will be on hand to make sure that these



Professor Greenberger speaks at the National Press Club in Washington, D.C.

special populations are included in the exercise and to evaluate the State's effectiveness in serving them during an emergency.

Meghan Butasek '10, a former CHHS staff member and current Director of Public Health Preparedness and Response for the Baltimore City Health Department, has researched the needs of foster care children and the foster care system during disasters. Her article "Information Sharing and Emergency Coordination Manual for Children in Foster Care Displaced by Disasters," appears in the book *Children, Law, and Disasters: What We Have Learned From the Hurricanes of 2005*, published by the University of Houston Law Center's Center for Children, Law & Policy and the American Bar Association.

CDC Strategic National Stockpile and Cities Readiness Initiative

The Baltimore City Health Department has asked CHHS to assist with its Strategic National Stockpile (SNS) and Cities Readiness Initiative (CRI) planning. The SNS is a national repository that is maintained by the Centers for Disease Control (CDC). It includes secretly located quantities of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration materials, airway maintenance supplies, and medical/surgical items to protect the public if a health emergency is severe enough to deplete local supplies. The CRI is a CDC-funded program that helps certain metropolitan areas, including Baltimore, coordinate and administer stockpiled supplies. State health departments and CRI cities are responsible for developing their own plans for distribution of materials through “points of dispensing.” The goal of SNS and CRI planning is to be able to distribute all the supplies to identified populations within 48 hours.

Pursuing Shelf Life Extension Program for Local Governments

Joshua Easton, a CHHS staffer and member of the Baltimore Urban Area Homeland Security Working Group, is putting his legal training to work on a mass prophylaxis initiative in Anne Arundel County, Maryland. The county, on behalf of regional first responders, has stockpiled a cache of pharmaceuticals that will reach their expiration date in two years. Easton has been working to get FDA approval to extend the expiration dates of these drugs through a testing program the FDA utilizes to extend the efficacy of military pharmaceutical caches. This program could provide a lower cost alternative to replenishing an entire local prophylaxis cache at the end of its shelf life, which would decrease

demands on limited homeland security resources.

According to Director Greenberger, CHHS expects to continue growing in the area of public health preparedness, aided substantially by its increased efforts in developing programs to prepare vulnerable populations for catastrophic emergencies.

Public Health Preparedness

Cont. from p. 5

¹⁷ *Id.*

¹⁸ M. Lichtveld, J. Hodge Jr. et al., *Emerging Issues in Public Health and Law: Preparedness on the Frontline: What’s Law Got to do with it?,”* 30 *J.L. Med. & Ethics* 184, Fall 2002.

¹⁹ Hogan, R. et. al., “Assessing Cross-Sectoral and Cross-Jurisdictional Coordination for Public Health Emergency Legal Preparedness,” *J.L. Med. & Ethics*, Supplement to Vol. 36:1, 36 (Spring 2008).

²⁰ Robert T. Stafford Disaster Relief and Emergency Assistance Act, PL 100-707, signed into law November 23, 1988; amended the Disaster Relief Act of 1974, PL 93-288.

²¹ 6 U.S.C.A. § 112 (West Supp. 2005).

²² DHS, National Response Plan (NRP) (December 2004) at v-viii, available at <http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf> (last visited March 21, 2008).

²³ NRP *supra* note 22 at 44.

²⁴ The authority for the federally directed medical assistance under the NRP is set forth in the NRP’s Emergency Support Function Annex #8, “Public Health and Medical Services.”

²⁵ See e.g., M. Greenberger, “The Role of the Federal Government in Response to Catastrophic Health Emergencies: Lessons Learned from Hurricane Katrina,” Working Paper, 2005 (on file with author) and D. Feinberg, “Hurricane Katrina and the Public Health-Based Argument for Greater



CHHS Attorneys participate in Emergency Preparedness Exercise

Federal Involvement in Disaster Preparedness and Response,” 13 *Va. J. Soc. Pol’y & L.* 596 (2006).

²⁶ *Id.*

²⁷ L. Gostin, *The Model State Emergency Health Powers Act: Public Health and Civil Liberties in a Time of Terrorism*, 13 *Health Matrix* 3, 10 (2003).

²⁸ Kouzoukas, D., “Public Health Emergency Legal Preparedness: Legal Practitioner Perspectives,” *J.L. Med. & Ethics*, Supplement to Vol. 36:1, 18 (Spring 2008).

²⁹ Bullard, C., et. al., “Improving Cross-Sectoral and Cross-Jurisdictional Coordination for Public Health Emergency Legal Preparedness,” *J.L. Med. & Ethics*, Supplement to Vol. 36:1, 57, 58 (Spring 2008).

³⁰ *Id.* at 58.

³¹ O’Brien, D., et. al., “Improving Information and Best Practices for Public Health Emergency Legal Preparedness,” *J.L. Med. & Ethics*, Supplement to Vol. 36:1, 64 (Spring 2008).

³² *Id.* at 65.

³³ *Id.* at 67.

ALUM WORKING ON EMERGENCY PREPAREDNESS

Erin Hahn thought she had taken her last major test when she graduated from law school in 2002. She didn't know that she'd continue being tested every day when she chose emergency preparedness as a career several years later. In 2007, Erin was tapped to serve as a Planner and Project Manager for the Maryland Emergency Management Agency (MEMA). Erin is charged with representing Maryland's interests in catastrophic planning efforts in the National Capital Region (NCR). The NCR is comprised of the District of Columbia; Montgomery and Prince George's Counties in Maryland; Arlington, Fairfax, Loudon, and Prince William Counties in Virginia; and all cities located on the outer boundaries of these counties. Disaster planning for this 6,000 square mile area is extremely difficult and a major test for people in the emergency planning field for a number of reasons—not the least of which is the challenge of coordinating across 11 local jurisdictions, two states, the District of Columbia, and the three branches of the Federal Government. In addition, included in the NCR are 4.2 million citizens, an average of 20 million tourists per year, 231 federal departments and agencies, 340,000 federal workers (11% of all federal workers), two major airports, the second largest rail transit system and the fifth largest bus network in the U.S.

Currently, NCR's efforts focus on evacuation and mass sheltering coordination. Erin is also working closely with representatives from Maryland, the District of Columbia, Delaware, Pennsylvania, Virginia, and West Vir-

ginia on regional catastrophic evacuation planning and is part of a regional executive committee and regional working group designed to enhance regional preparedness efforts generally.

Prior to taking on her current role, Erin served as Associate Director of the Center for Health and Homeland Security (CHHS) from 2006 to 2007, after working as a staff attorney at the Center. As the Associate Director, she helped manage the daily operations of the Center and helped foster its rapid growth from a three-person shop in 2002 to nearly 50 employees in 2008.

Although emergency preparedness



Erin Hahn

is by its very nature interdisciplinary, Erin considers herself a health lawyer. She noted that a common theme running through all emergency preparedness is protection of the public's health. Her legal knowledge of the local, state and federal health care systems has been very helpful in her career. One of the specific health-law related questions she has tackled is quarantine. Although, as she notes, the laws regarding quarantine were on

the books prior to 9/11 and Katrina, there is a great degree of uncertainty in the public health community about the proper methods for carrying out quarantine. As an attorney at the Center, Erin assembled handbooks and scheduled training sessions for local decision makers, health commissioners, first responders, and the Governor on the issue of quarantine. She also worked on the often conflicting legal, ethical, and epidemiological perspectives of vaccine and medical supply distribution in the time of an infectious disease outbreak. As part of this investigation, she looked into the issue of compelled vaccination which, although allowed under Maryland law, is a sensitive issue and one that CHHS staff has been asked to clarify and explain to state decision makers. Erin addressed these and other health related legal questions as one of the editors of the *Maryland Public Health Emergency Preparedness Legal Handbook*, a comprehensive guide to the relevant statutes and regulations pertaining to emergency response.

Aside from her legal training, Erin commented that one of the most helpful skills that an emergency planner can have is the ability to see both the big picture while maintaining "situational awareness" in order to put the small pieces together in an emergency. This ability will be essential as she faces the challenge of helping coordinate emergency preparedness in the nation's capital with her new position at MEMA.

IN THE CLINIC

The University of Maryland School of Law's Clinical Law Program is ranked as one of the top in the country. Contributing to the Program's success are several health law clinics. Each of these clinics performs valuable work in our community and has affected health care practices and policies at the local and state level. The following article, which appeared in the Daily Record, highlights the work of two of our clinics: Health Care Delivery and Child Welfare Legal Issues Clinic: The Challenge of the AIDS Epidemic and the Interdisciplinary Practice With Grandparent Families Clinic.

Of Service: HIV clinic is an eye-opener for UM law students

Lawyers in training at the University of Maryland School of Law's HIV Legal Representation Project and the Interdisciplinary Practice Clinic represent clients in a wide variety of legal issues, including contested custody, family law, public benefits and debt collection. Typically, eight to 10 students in the year-long clinic represent seven or eight clients each.

While the legal remedies they provide are invaluable to clients with dire legal needs, the students also are picking up valuable skills that will serve them in their careers.

"The students learn how to interview clients, how to build relationships of trust and how to counsel in sensitive issues," said Deborah Weimer, the law professor who has managed the clinic for 19 years. "The goal is to sensitize them to people who are poor and don't have access to a lawyer — and who are needy, marginalized and without resources."

For most of Weimer's students, the experience is eye-opening. "They see what it means to be poor in Baltimore," she said. "And often they're surprised by how clients survive in really challenging circumstances."

A case in point: Grandparents pursuing legal custody or adoption of children whose parents have died or been incapacitated by AIDS. "We've always represented third-party care-

givers — grandparents, aunts, uncles, older brothers and sisters — in custody proceedings," Weimer said. "These families face a lot of challenges."

The clinic has teamed up with the University of Maryland School of Social Work in a program called Grandparent/Family Connections. "Often, grandparents have to deal with their own health issues as well," Weimer noted. "The program provides support to grandparents so that the grandchildren don't end up in foster care."

Student attorneys have developed workshops for grandparents raising their grandchildren to help them with their legal choices and give them information on public benefits that are available. "Often, mom is too sick to raise the child and grandma wants to step in to make sure custody goes to her," Weimer said.

"We also meet with families to figure out what services would be most beneficial," she continued. "For example, one client's house was being sold for back taxes, so we found her a pro bono lawyer to help with the bankruptcy filing. We also work a lot with schools, helping kids with special needs."

Frequently, grandparents apply for Temporary Cash Assistance only to be told by the Department of Social Services — incorrectly — that they must fulfill a work requirement to qualify.

"Given that they are volunteering to

care for grandchildren, often in very stressful circumstances, they should not be compelled to work outside the home for this very small amount of money at a time when they are taking a difficult job of parenting children who just lost one or both parents to illness, death or drug addiction," Weimer said.

The clinic is also addressing the needs of another distressed group — inmates with HIV who complain about disclosure by prison staff.

"Inmates have a particularly hard time getting care in a private setting," Weimer explained. "In one case, an 18-year-old boy heard his name called out and refused to get his medication. It's because of shame and fear of the other inmates' reaction. There's a real stigma attached to having HIV with other prisoners."

To correct the problem, the students are working with the warden over the lack of concern for privacy. "There are lots of reasons prison is awful," Weimer added. "This is another."

Prisoners and their families are also stymied by the increased difficulty of arranging medical parole for those with HIV. "Even with all the new drugs, some people are still very sick, but not about to die," Weimer explained. "And that's a good thing. But it makes it harder to get them out on a medical parole."

Cont. on page 20

DHMH SECRETARY MEETS WITH STUDENTS AND FACULTY

John Colmers, Secretary of the Maryland Department of Health and Mental Hygiene (DHMH), visited the law school in March to meet with faculty members whose research and clinical work intersects with DHMH, and to talk to students about the Department and his goals as Secretary.

Colmers met with faculty representatives from the Law & Health Care Program, the Center for Dispute Resolution, the Center for Health and Homeland Security, the Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, and the Maryland Healthcare Ethics Committee Network. He also met with the faculty members who run the Drug Policy and Public Health Strategies Clinic, the AIDS Clinic, and the Interdisciplinary Grandparent Families Clinic.

In his meeting with students, Colmers explained the four roles of DHMH—insurer, provider, regulator, and protector of public health—and how

DHMH's 8,000 employees carry out those roles. He also detailed his goals as Secretary: to improve access to health care and expand health coverage; to improve quality of care; and to foster the next generation of Maryland public health professionals. Colmers stated that his goal is to make DHMH a "teaching hospital" for health policy and public health students, using the Department to train future public health leaders the same way a hospital trains future health care providers.

Before he was nominated to his present position, Colmers was a Senior Program Officer for the Milbank Memorial Fund. The New York-based Fund is an endowed national foundation that provides nonpartisan analysis, study, research, and communication



John Colmers (center) with Professor Hoffmann and students.

on significant issues in health policy. Before joining the Fund, he spent 19 years in Maryland State government where he held various positions, including Executive Director of the Health Services Cost Review Commission, the agency overseeing Maryland's all-payer hospital rate setting system. He has a BS from the Johns Hopkins University and an MPH from UNC Chapel Hill.

CREATING TIES WITH THE MEDICAL SCHOOL— PERSONALLY AND PROFESSIONALLY

On April 2, the School of Law's Student Health Law Organization (SHLO) held a mixer with University of Maryland Medical School students in an attempt to bridge the gap—real or perceived—between both groups of students and between both professions. Bridging the gap is less of a problem for this year's President of SHLO Emily Dubansky, who is married to 2nd year University of Maryland medical student Josh Dubansky. While Emily is taking the lead in organizing activities for students interested in health law, Josh heads up the medical school's chapter of the American Medical Students Association (AMSA).

As part of the mixer, Emily organized a tour of University of Maryland's nationally-recognized Shock

Trauma Center. The Center was founded in 1961 by heart surgeon and shock researcher R. Adams Cowley who believed that trauma patients would benefit greatly if they were treated appropriately in the "golden hour" after trauma. Students toured the wards of the Center, which is the first and only hospital dedicated solely to trauma care in the United States.

After the tour, both student groups met for a wine and cheese reception that featured a talk by the Secretary of Maryland's Department of Mental Health and Hygiene, John Colmers, who recently visited the law school (see article above).

How was it planning a joint event with her husband? Emily said it went very smoothly. "Because of our relationship, I get a glimpse into the medi-

cal profession on a daily basis, which is something most attorneys never get to experience," she said. "Josh also has a perspective on the legal profession that is very different from most physicians. Planning this event was especially gratifying because we got to see other medical and law students find common ground by discussing health policy issues that we all care deeply about."



Emily & Josh Dubansky

L&HCP SPONSORS CONFERENCE ON THE ETHICS OF HEALTH CARE REFORM

On April 7, the Law & Health Care Program held a conference on “The Ethics of Health Care Reform.” The focus of the conference was the ethical underpinnings and consequences of certain key components of health care proposals being put forward by the presidential candidates and other policy makers. The goal was to go beyond mere descriptions of different approaches to health care reform and to provide some analysis of the ethical bases of various reform strategies, including the individual mandate, wellness programs and payment for performance.

Ezekiel J. Emanuel, MD, PhD, Director of the Clinical Bioethics Department at the National Institutes of Health, delivered the keynote address. He described the health care reform proposal he has developed in collaboration with Victor R. Fuchs called Guaranteed Healthcare Access. The plan would ensure that every American receive a certificate to obtain a standard benefits package through an insurance company or health plan. It would be funded by a value added tax and would require the eventual phasing out of Medicare, Medicaid, and SCHIP.

Following Dr. Emanuel’s talk, conference participants heard from

a number of nationally-recognized health policy experts and health law faculty. Gregg Bloche, Co-Director of the Georgetown-Johns Hopkins Joint Program in Law and Public Health and Professor of Law at Georgetown, spoke about the various health care reform proposals currently being offered by the presidential candidates and his thoughts about the likelihood of achieving health care reform in the near future. Ruth Faden, Professor and Executive Director of the Johns Hopkins Berman Institute of Bioethics, discussed the moral assumptions underlying Democratic and Republican health care reform proposals. Professor Diane Hoffmann, Associate Dean of the University of Maryland Law School and Director of the Law & Health Care Program, spoke on the ethics of the individual mandate. University of Southern Illinois Law School Professor Marshall Kapp provided an alternative view of health care reform in his talk on consumer-driven health care. As the day’s final speaker, Dr. Marion Danis, the Head of the Section on Ethics and Health Policy in NIH’s Department of Bioethics, presented “Health Care Reform Beyond Health Insurance,” in which she discussed the importance of recognizing all of the social indicators of health status when developing propos-



Ezekiel Emanuel

als for health care reform, many of which are not addressed by the reform proposals of the current presidential candidates.

The conference was jointly sponsored by Harbor Hospital and The Center for Health Program Development and Management at the University of Maryland, Baltimore County (UMBC), and supported by a grant from the Leonard C. Homer / Ober|Kaler Law & Health Care Fund. The agenda and webcasts of presentations are available at <http://www.law.umaryland.edu/programs/health/mhecnc/conference.html>.

STUDENT HEALTH LAW ORGANIZATION HOSTS “SPEED NETWORKING” EVENT

This year, the Student Health Law Organization (SHLO) sponsored a number of activities for students interested in health law, including the annual Spring Networking Event, a signature event of the Law & Health Care Program and SHLO that brings together health law alums and students to enjoy dinner and networking. This year’s event featured something new—speed networking. Based on the popular speed dating concept, students and alums had a few minutes to network before a bell rang and everyone shifted seats to network with the next person in line. A wide variety of health law practitioners attended the event including attorneys from the Maryland Board of Pharmacy, private practice, the National Human Genome Research Institute, MedStar Health, Bon Secours Health System, and Johns Hopkins Medical Systems Corporation.

HEALTH LAW STUDENTS AND FACULTY TRAVEL TO CHINA

During the law school's spring break, a delegation of students, faculty, and alumni traveled to China for a week of both tourism and meetings with Chinese government officials, representatives of several law schools, law firms, and the World Health Organization. The trip was conceived and organized by law school Professor Robert Percival, who is teaching in Beijing during Spring Semester 2008 as a J. William Fulbright Scholar at the China University of Political Science and Law. In addition, Visiting Professor Daniel Mitterhoff, a professor at the Law School of the Central University of Finance and Economics (CUFE) in Beijing, was instrumental in organizing a number of fascinating health policy-related visits for the Maryland group.

Along on the trip were a number of students and faculty members from the Law & Health Care Program, including Program Director Diane Hoffmann and Dean Karen Rothenberg. The timing of the trip—just before China hosts the 2008 Olympic Games—provided an interesting health-related backdrop for the group's visit given the attention that the Olympics is bringing to air pollution and cigarette use. Ubiquitous during the trip were images of the five Fuwa (or mascots) of the games. A short time before the Maryland contingent arrived in China, a fictitious letter from one of the Fuwa appeared in the newspaper urging Chinese citizens to quit smoking. This is part of WHO's campaign to decrease tobacco use in the country, which includes prohibiting taxi drivers from smoking in their cars during the Olympics.

Tobacco use was one of the subjects addressed at a meeting that the

Maryland delegation had at WHO's Beijing Office. Dr. Sarah England, the Technical Officer in the Tobacco Control Initiative, told the group that the Beijing Olympics has provided a unique opportunity to coax the Chinese government towards greater tobacco control. WHO is working with the Beijing Municipal Government on regulations to ban smoking in public places (or at least Olympic venues), which they hope to issue at the end of May. WHO representatives also gave their perspective on the issues of organ transplantation, intellectual property and drug development, and HIV/AIDS in China and discussed how the WHO is working with Chinese officials to



The Maryland delegation at the Forbidden City

address these issues.

The health law group also had a unique opportunity to meet with high level officials from China's Ministry of Health (MOH) including Zhao Ning, an attorney and the Director of MOH's Division of Health Regulation, and Zhou Jian, a physician and Director of MOH's Department of External Relations & Projects Management at the International Health Exchange and Cooperation Center. The officials hosted the Maryland delegation in a large, formal meeting hall with an enormous mural of the Great Wall of China. Both showed power point presentations that gave the delegation a candid

and thorough overview of the Chinese health care system and the challenges it is facing, as well as the myriad of laws and regulations governing health care in China.

A number of U.S. health policy experts have been writing about the Chinese health care system in the last year. Articles have appeared in the *Economist* and *Health Affairs* that describe China's commitment to improving health care while facing the "double-edged sword of having both a large uninsured population and rapid health care cost inflation."¹ The MOH officials who met with the Maryland group echoed these views and noted that while the goal of the Chinese government is universal health coverage, a great deal of reform and money will be required to reach this goal.

With the collapse and privatization of state-owned enterprises, the vast majority of citizens have been left with no health insurance. In 2003, the government introduced a new medical insurance program in the countryside. This program involves contributions from rural residents as well as local governments and, for the first time, the central government. The number of people taking part rose from 80 million that year to more than 730 million now. The eventual goal is to include all rural residents, who number about 800 million according to official figures.² Commentators have noted that this program is only a slight relief, if at all, for the poor because it often does not cover routine outpatient treatment. In addition, the average reimbursement rate is only 30-40%, and bills have to be paid in full prior to treatment. Because of this stipulation, hospital stays are beyond the means of many.

An additional ongoing concern that

the MOH officials shared is addressing health coverage for the urban unemployed. In China's growing industrial cities, employers are required to provide insurance but unemployed individuals or informally hired migrant workers who are living away from their home provinces have no coverage. The government is currently taking steps to cover this group.



L&HCP Director Diane Hoffmann, Dean Karen Rothenberg and Becky Seltzer

In 2005, the government established community health centers in urban areas to provide prevention, primary care, home care, and rehabilitative services.³ The aim is to have every urban citizen covered by 2010.⁴

Mr. Zhou and Ms. Zhao also discussed medical malpractice in China, highlighting a recent high profile case in which, according to anecdotal information, a husband refused to sign a consent form the hospital required prior to permitting his incapacitated wife to undergo a cesarean section. The mother later died and the baby did not survive. The deceased woman's relatives are suing the hospital for failure to perform the procedure over the husband's objections and the husband for not consenting to the C-section. The case has not yet been resolved, but provided an interesting introduction to the topic. Historically, there has been very little malpractice litigation

in Chinese courts. Most disputes are handled through an administrative process, but the MOH is also experimenting with ADR, and establishing several mediation pilot projects in a number of cities to handle medical malpractice disputes.

Mr. Zhou also spoke about the changing picture of morbidity and mortality in China. China is facing a problem that is common to developing nations. As the population becomes richer and has greater access to modern medicine, fewer people are dying of infectious diseases and more are living long enough to develop cancers. Cancer is now the leading cause of death in China and one that is forcing health officials to improve access to cancer treatments and the treatment of pain associated with cancer.

In addition to having the opportunity to learn about the Chinese health system from Chinese and WHO officials, the Maryland delegation was treated to receptions hosted by law firms DLA Piper and Hogan & Hartson in Beijing and the Maryland Department of Business and Economic Development in Shanghai.

The group also had the chance to visit some of China's most famous tourist destinations. The group toured Beijing, which included visits to the Temple of Heaven, the Summer Palace, and the Forbidden City. The group also visited the Great Wall of China and the terra cotta warriors in Xi'an – a spectacular collection of 8,000 life-sized warriors and horses buried alongside Emperor Qin Shi Huangdi, founder of the Qin Dynasty, who died in 206 B.C.

The final stop was Shanghai, a

thriving metropolis that tour participants likened to a modern Manhattan



Health Law Students Anne Tinoco '10 and Roselle Chatsuthiphan '10 at the Ministry of Health

but much newer and much bigger. In Shanghai, the group visited the JinMao tower (the tallest building in China); walked along the Bund with grand colonial buildings from when the French, British and Americans had set up their own trading concessions and were governed by their own police forces and judiciary; the Jade Buddha Temple and the beautiful Yu Gardens. A highlight of their time in Shanghai was a night cruise along the Huangpu River.

According to Diane Hoffmann, the trip was a wonderful opportunity to learn about some of the health and environmental problems facing China as well as a chance to get to know a great group of students interested in health and environmental law.

References

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³ Yip et al. *supra* note 1.

⁴ "Losing Patients," *supra* note 2.

L&HCP ALUM AND ADJUNCT PROFESSOR TAKES LEAD ROLE IN CRAFTING STARK III REGS

University of Maryland School of Law alum and adjunct professor Lisa Ohrin ('94) is having a busy year. As Deputy Director of the Division of Technical Payment Policy within the Center for Medicare Management at CMS, Ohrin was one of the principal drafters of Phase III of the regulations implementing the physician self-referral (the "Stark") law, which were published on September 5, 2007 and went into effect on December 4, 2007 (the "Phase III final rule"). She also assisted in the drafting of the Calendar Year (CY) 2008 Physician Fee Schedule Proposed and Final Rules which were published on July 12, 2007 and November 27, 2007, respectively.

The Stark Law (42 USC 1395nn) is actually three separate provisions and governs physician self-referral for Medicare and Medicaid patients. Congress included a provision in the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) which barred self-referrals for clinical laboratory services under the Medicare program, effective January 1, 1992. This provision is known as "Stark I." The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid. This legislation, known as "Stark II," also contained clarifications and modifications to the exceptions in the original law. "Stark III" is the final rule that was recently published. Regulations relating to self-referral are also set forth in other contexts such as the Physician Fee Schedule.

The Phase III final rule and the 2008 Physician Fee Schedule made significant changes to the regulations that govern physician referral practices and have been the subject of a great deal

of commentary within the health law community. Most of the proposals in the CY 2008 Physician Fee Schedule were not finalized and remain under consideration by CMS for publication in an upcoming rulemaking. Proposals still under consideration by CMS would have a dramatic effect on the



Lisa Ohrin

relationships between physicians and the health care entities (especially hospitals) to which they refer Medicare patients for designated health services. In fact, the attorney members of the American Health Lawyers Association (AHLA) placed the proposed and final changes to the physician self-referral rules at the top of the AHLA's list of the Top Ten Health Law Issues for 2008.

Ohrin has been asked to speak to numerous groups, including a number of state bar associations and trade associations for both lawyers and the health care industry, regarding the final rules. She has also described her participation in the drafting process to health law students at the law school.

Although Ohrin's time has been devoted primarily to drafting these three rules, she is also responsible for issuing advisory opinions regarding the physician self-referral prohibition, overseeing enforcement of Medicare-approved transplant centers, and handling a variety of statutory and regulatory Medicare payment issues. As part of her duties, Ohrin briefs members of Congress and congressional committee staff members regarding CMS rules on all aspects of the physician self-referral law, and provides technical assistance on proposed legislation.

Ohrin has 14 years of experience in the field of health law. Prior to working at CMS, she worked for Beth Israel Deaconess Medical Center in Boston as Assistant General Counsel, here at the law school as a Faculty Lecturer and Coordinator of the Law & Health Care Program, at Ober, Kaler, Grimes & Shriver in Baltimore, ManorCare Health Services in Gaithersburg, Maryland, and Dimensions Healthcare System in Landover, Maryland. She also worked as a Legislative Analyst for the Department of Legislative Reference in Annapolis, Maryland, during the 1994-1995 session of the Maryland General Assembly. These varied health law experiences make her an invaluable asset to the Law & Health Care Program's adjunct faculty. According to Ohrin, many of the career opportunities that have come her way are a direct result of her relationship with the Law & Health Care Program, including Dean Rothenberg recommending Ohrin for her first in-house counsel position and Associate Dean Hoffmann's mentoring Ohrin's development as an adjunct professor. "I am so grateful for the Law & Health Care Program and the positive impact being associated with the Program has

had on my career,” said Ohrin. “Many of my former students are now colleagues, which continues to astound me. I watch as they progress in their

own careers, tackling incredibly difficult subject matter areas, such as the physician self-referral laws, and I am certain that much of their success, as

is mine, is due to the excellent training and practical experience they obtained through the Law & Health Care Program.”

Key Provisions of the Phase III Regulations and the 2008 Physician Fee Schedule

“Stand in the Shoes.” A physician’s relationship with an entity providing designated health services (such as a hospital) through a direct single intervening physician organization (such as a group practice) may no longer take advantage of the Stark law’s indirect compensation exception. The physician is deemed to “stand in the shoes” of his or her physician organization and have the same compensation arrangements on the same terms and with the same parties as the physician organization. Therefore, the relationship between the physician organization itself and the entity providing designated health services must meet an exception to the prohibition on physician self-referral.

Shared Space. To the extent a physician or practice utilizes the Stark law’s in-office ancillary services exception to provide designated health services to patients (such as imaging or clinical lab services), such services arguably must be provided in space that is leased on a block-time basis, rather than a per-click basis.

Independent Contractors. Group practices which obtain the services of an independent contractor physician (such as a pathologist or radiologist) in connection with the provision of designated health services must contract with that physician directly rather than with the physician’s practice or a staffing service, if the physician is to be considered a “physician in the group.”

Recruited Physicians. The regulations expand the exception for recruitment payments to provide additional flexibility for recruiting physicians. In addition, when the recruited physician joins a group practice, the group may impose a non-compete restriction on the recruited physician under certain circumstances. Such non-compete agreements were previously prohibited. Similar flexibility was added to the exception for retention payments.

Academic Medical Centers. Under the Stark law, academic medical centers are provided with an exception that gives greater latitude to specific compensation payments as long as the aggregate compensation paid is at fair market value. The Phase III regulations make some clarifications to this exception. Key clarifications are (i) the requirement to aggregate physician faculty member compensation relationships in order to determine fair market value and (ii) the method for counting faculty member physicians.

Productivity Bonuses. The Phase III regulations clarify that payment of a productivity bonus to a physician may be based directly on services that are performed “incident to” the physician’s services, even though the “incident to” services may be referrals for purposes of the statute.

Fair Market Value. The fair market value exception has been expanded to include arrangements whereby a physician makes payments to an entity providing designated health services (such as a payment for health services). Previously, the exception covered only payments from the entity to the physician for items or services provided by the physician to the entity.

Amendments to Agreements. The Phase III regulations clarified that amendments to agreements implicated by the Stark law are acceptable, provided that the economic elements of the agreement (such as the rate of physician compensation or the square footage of a lease) remain unchanged by the amendment.

Kathleen Dachille

PRESENTATIONS

“A Review of the Common Law Tort of Nuisance,” Multi-Unit Housing Ancillary Meeting: SHS As Nuisance: Is Common Law Sufficient or Should Statutory Provisions be Pursued?, Minneapolis, MN (October 2007).

“Secondhand Smoke in a Multi-Unit Housing Setting,” National Conference on Tobacco or Health: Smoke-Free Housing: The Next Frontier is Here, Minneapolis, MN (October 2007).

“Legal Issues Surrounding the Sale of Tobacco Products in Baltimore City and the State of Maryland,” Baltimore City Youth Forum: Black and Mild, Baltimore, MD (October 2007).

“The Maryland Clean Indoor Air Act,” MdQUIT Second Annual Conference, Ellicott City, MD (December 2007).

Q & A Session on Federal, State and Local Tobacco Control Policy in the U.S. with Delegation of Russian Doctors and Public Health Advocates, University of Maryland Medical School, Baltimore, MD (February 2008).

“Tobacco Control Legislation in Maryland: A Role for Young Advocates,” TRASH—Teens Rejecting Abusive Smoking Habits—Meeting, Baltimore, MD (February 2008).

“Legal Strategies to Address Secondhand Smoke Exposure in the Home” and “Interventions to Protect Children from SHS in Private Places,” Access Seattle conference, Seattle, WA (March 2008).

“Legislative Responses to the Dynamics of Cigar Use,” Beyond Cigarettes: Policy Responses to Other Tobacco Products (conference), Columbus, OH (April 2008).

Michael Greenberger

PRESENTATIONS

“Emergency Public Health Law Issues,” Briefing before Council of the Special Committee on Bioethics and the Law, American Bar Association Annual Meeting, San Francisco, CA (August 11, 2007).

“Emerging Biodefense Issues: Legislative, Contractual and Risk Allocation,” American Bar Association Public Contract Law Biodefense Panel, American Bar Association Annual Meeting, San Francisco, CA (August 12, 2007).

“Maryland Public Health Emergency Benchbook” and “Continuity of Operation Plans” for the Administrative Office of the Courts (September 28, 2007), the Cabinet of Maryland Judicial Council (October 17, 2007), and the Maryland Judicial Council, Annapolis, MD (October 18, 2007).

“Pandemic Preparedness and Civil Liberties,” American Civil Liberties Union Press Conference, National Press Club, Washington, DC (January 14, 2008).

“Food Safety—Hardening Defenses against Bioterrorism and Natural Disasters,” Third Annual Homeland Security Institute hosted by the American Bar Association Section of Administrative Law and Regulatory Practice, Washington, DC (January 18, 2008).

“Germ Warfare, Contagious Disease, and the Constitution,” Speaker, Stanford Constitutional Law Center and

the Constitution Project Symposium, Washington, DC (April 11, 2008).

PUBLICATIONS

Maryland Public Health Emergency Benchbook (September 28, 2007).

MEDIA/INTERVIEWS

“How did Tuberculosis Infected Man Leave Atlanta,” WVON Radio (Chicago), KNX Radio (Los Angeles) (June 1, 2007) and WTWP Radio 1500 AM (June 7, 2007).

“Local Pandemic Preparation Lacking,” *Medill News Service* (published in nine newspapers and 12 web sites) (January 20, 2008).

“U.S. Flu Outbreak Plan Criticized,” *Washington Post* (February 2, 2008).

“ACLU Stresses Public Health’s Role in Pandemics,” *AMEDnews.com* (February 4, 2008).

Deborah Hellman

PRESENTATIONS

“Prosecuting Doctors for Trusting Patients” presented at Faculty Workshops at Rutgers-Camden School of Law (November 2007); University of Pennsylvania Law School (January 2008); Center for Bioethics, University of Pennsylvania (February 2008); Arizona State Law School, Center for Law and Philosophy (March 2008).

PUBLICATIONS

“Pushing Drugs or Pushing the Envelope: The Prosecution of Doctors in Connection with Over-Prescribing of Opium-Based Drugs,” *Philosophy & Public Policy Quarterly*, Vol. 28, Winter/Spring 2008, 7-12.

Diane Hoffmann

PRESENTATIONS

“Hospital Acquired Infections – A New Battleground Over Health Information,” 30th Annual Health Law Professors Conference, Boston University School of Law, Boston, MA (June 1, 2007).

“Influencing Federal and State Policy Makers,” Annual Meeting of the American Society of Reproductive Medicine, Washington, DC (October 16, 2007).

“Is Dying a Public Health Issue?” Conference on Public Health Perspectives On Charged Legal Issues, Widener University School of Law, Wilmington, DE (October 19, 2007).

“Legal Issues in the Use of Opioid Analgesics for Pain Treatment,” Conference: Helping Clinicians Manage Pain Safely: A Clinical and Regulatory Review for Risk Reduction, St. Raphael Hospital, New Haven, CT (October 25, 2007).

“Building Public Health Law Capacity at the Local Level,” PHLA Summit on Building Capacities and Communication Linkages in Public Health Law, Washington, DC (November 4, 2007)

“Are Health Care Conflicts More Difficult Than Other Types of Conflicts? A Contrarian View” at “An Intentional Conversation About Conflict Resolution in Health Care,” Hamline University School of Law, Saint Paul, MN (November 9, 2007).

“The Ethics of the Individual Mandate,” Conference on the Ethics of Health Care Reform, University of Maryland School of Law, Baltimore, MD (April 7, 2008).

“Implications of the Second Generation of Genetic Tests in the Courtroom,” at Translating ELSI conference, Case Western University, Cleveland, OH (May 3, 2008).

PUBLICATIONS

“Judging Genes: Implications of the Second Generation of Genetic Tests in the Courtroom” (with Karen Rothenberg), 66 *Maryland Law Review* 858 (2007).

Building Public Health Law Capacity at the Local Level” (with Virginia Rowthorn) (commissioned paper), Public Health Law Association (September 2007).

“Achieving Quality and Responding to Consumers—The Medicare Beneficiary Complaint Process: Who Should Respond?” (with Virginia Rowthorn) (forthcoming *Indiana Health Law Review*).

“Are Health Care Conflicts all that Different? A Contrarian View” (forthcoming *Hamline Journal of Public Health Law & Policy*).

MEDIA/INTERVIEWS

“DNA Tests Offer Deeper Examination of Accused: Biological, Emotional States Scrutinized,” *Washington Post* (April 20, 2008).

Karen Rothenberg

PUBLICATIONS

“Judging Genes: Implications of the Second Generation of Genetic Tests in the Courtroom” (with Diane Hoffmann), 66 *Maryland Law Review* 858 (2007).

MEDIA/INTERVIEWS

“DNA Tests Offer Deeper Examination of Accused: Biological, Emotional States Scrutinized,” *Washington Post* (April 20, 2008).

Ellen Weber

PRESENTATIONS

“Clinical Health Law Teaching,” 30th Annual Health Law Professors Conference, Boston, MA (June 1, 2007).

“Drug Addiction in Today’s Baltimore,” Baltimore City House and Senate Delegation, Baltimore, MD (October 16, 2007).

PUBLICATIONS

“Child Welfare Interventions for Drug-Dependent Pregnant Women: Limitations of a Non-Public Health Response,” 75 *UMKC L. Rev.* 789 (Spring 2007).

OTHER ACTIVITIES/APPOINTMENTS/AWARDS

American Association for the Treatment of Opioid Dependence, Nyswander-Dole Award (October 23, 2007).

MEDIA/INTERVIEWS

“Drug Clinic Limit Stands: Baltimore County to Maintain Zoning Restrictions on Methadone Facilities,” *Baltimore Sun* (February 24, 2008).

“Zoning Rules Revisited: City Considers Easing Laws on Treatment Center Placement,” *Baltimore Sun* (January 7, 2008).

In the Clinic

Cont. from p. 11

Much of the clinic's work centers around family law — including CINA cases where the student lawyers (all of whom work under the supervision of Weimer or a clinical instructor) represent family members who want to step in when the mother is too sick to care for her children and ensure that the children don't end up in foster care.

An example: An HIV-positive client learned she had the disease when she gave birth to her son. Severely depressed at the news they were both HIV+, she had a hard time complying with her new son's strict medication regimen.

As a result, she was charged with medical neglect. "But we were able to get her reunified with her child," Weimer said.

Another example is a pregnant woman who tested positive for HIV when giving birth — and who also tested positive for marijuana. "The child was removed just for the marijuana, which isn't the same as cocaine or heroin," Weimer said. The student lawyer on the case was able to reunite the family.

While much of the news surrounding HIV/AIDS is bad — the number of HIV-positive people in Baltimore has doubled over the last decade, one of a handful of U.S. cities that has seen such dramatic increases — there's also some good news.

"Pregnant women who get prenatal care and treatment for HIV can prevent transmission to the child in

almost every case," Weimer said. "So only a handful of kids are now born with the disease."

Plus, blatant discrimination against those with HIV/AIDS is less common, she added: "But it's still out there."

And the epidemic continues to surge in some of Baltimore's poorest neighborhoods.

"That's mainly because of drug use and unprotected sex," Weimer said. "What we're trying to do in these clinics is provide support to families in poverty-ravaged neighborhoods and break the cycle of drug use and despair."

—Joe Surkiewicz, *The Daily Record*
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Comments and letters should be forwarded to the above address.