

# LAW & HEALTH CARE

PROGRAM



## FROM THE DIRECTOR

I hope you like our new look! We've changed our colors and updated our format. In this issue of the newsletter, we highlight two of our affiliated programs and the people who make them run: Michael Greenberger and Anita Tarzian. Professor Greenberger is Director of the Center for Health and Homeland Security and Dr. Tarzian is the Coordinator of the Maryland Healthcare Ethics Network. These two initiatives, along with the Network for Public Health Law, Eastern Region and the Center for Dispute Resolution at University of Maryland are a rich source of scholarship and collaboration for Law & Health Care Program faculty and students.

## PROFESSOR MICHAEL GREENBERGER AND THE CENTER FOR HEALTH AND HOMELAND SECURITY GOING STRONG AFTER 15 YEARS

The Center for Health and Homeland Security (CHHS), an affiliated Center of the Law & Health Care Program, is celebrating its 15th anniversary this year. What started in response to the terrorist attacks of September 11, 2001, has grown into a 50+ person legal and policy development shop with expertise in all the forms of disaster that threaten communities. At the time CHHS was started, Founder and Director Professor Michael Greenberger was often questioned on pairing "health" with "homeland security," but the inextricable relationship between the two issues has been proven over and over again as the Center has consulted on issues from bioterrorism and food safety, to pandemic influenzas, to natural disasters such as Hurricane Katrina. These events underscored the critical need to include public health and health care stakeholders in security and emergency planning of all kinds.



CHHS opened on May 15, 2002 as an initiative by University of Maryland Baltimore officials and CHHS Founder and Director Michael Greenberger



UNIVERSITY of MARYLAND  
FRANCIS KING CAREY  
SCHOOL OF LAW

## IN THIS ISSUE

Professor Michael Greenberger and the Center for Health and Homeland Security



Frank Pasquale Speaks at Nobel Prize Dialogue Tokyo 2017



Profile . . . Dr. Anita Tarzian, Coordinator of the Maryland Healthcare Ethics Network



Studying the Zika Pandemic from Global and Local Perspectives



Maryland Carey Law Wins Health Law Regulatory and Compliance Competition



2017 Stuart Rome Lecturer: Professor Nicolas P. Terry



The *Law & Health Care Newsletter* is published by the Law & Health Care Program at the University of Maryland Francis King Carey School of Law  
500 West Baltimore Street  
Baltimore, MD 21201

### **L&HCP Faculty**

Diane E. Hoffmann, JD, MS  
Director, L&HCP and Professor of Law

Richard Boldt, JD  
Kathleen Hoke, JD  
Sara Gold, JD (visiting)  
I. Michael Greenberger, JD  
Leslie Meltzer Henry, JD, PhD, MSc  
Frank Pasquale, JD, MPhil  
Amanda Pustilnik, JD  
Karen Rothenberg, JD, MPA  
Ellen M. Weber, JD  
Deborah J. Weimer, JD, LLM

### **Adjunct Faculty 2017-2018**

Stephen Carney  
Funk & Bolton, PA  
Marc Charmatz, JD  
National Association of the Deaf  
James Doherty, Jr., JD  
Pecore & Doherty, LLC  
W. Lawrence Fitch, JD  
Maryland Department of Health  
and Mental Hygiene  
Marshall E. Jackson, JD  
McDermott Will & Emery  
Janet Klein Brown, JD  
Office of the Attorney General  
Janet Lord, LLB, LLM  
Syracuse University College of Law  
Kathleen McDermott, JD  
Morgan, Lewis & Bockius LLP  
M. Natalie McSherry, JD  
Kramon & Graham  
Roann Nichols, JD  
Office of the United States Attorney  
John S. Nugent, JD  
Office of the Attorney General  
Frank Palumbo, PhD, JD  
University of Maryland  
School of Pharmacy  
Erik Roskes, MD  
Maryland Department of Health  
and Mental Hygiene  
Jack Schwartz, JD  
  
L&HCP Managing Director  
Virginia Rowthorn, JD  
MHECN Coordinator  
Anita Tarzian, PhD, RN

to provide policy development and legal analysis on homeland security issues following the 2001 attacks. The scope of work of the Center soon expanded and, by summer 2003, the Maryland Emergency Management Agency asked CHHS to develop a manual to guide Maryland state agencies through the Continuity of Operations (COOP) plan writing process in the case of any major disaster. Next, Howard County, MD, the Baltimore City Health Department, and the University of Maryland Medical Center tapped CHHS for its expertise in emergency planning. The rest, as they say, is history.

The Center now works with over 25 local, state and federal agencies to provide them with expertise and training in the areas of crisis management and cybersecurity. The Center also provides jobs for many law school graduates and externships for current law students. In addition to directing the Center and working extensively in homeland security and counterterrorism law, Professor Greenberger created and taught a popular seminar at the law school on the Law and Policy of Emergency Public Health Response. He also oversees the recently-created Masters of Science in Law's Homeland Security and Crisis Management track. This nascent graduate program is attracting individuals from both the public and private sectors who wish to learn about the law of crisis management and cybersecurity so that they can be more effective in their current jobs or move into a career in this hot new area.

Greenberger's expertise in public health emergency law is sought out, and he has appeared extensively as a presenter at national conferences,

speaking on all matters of public health topics, from the need to re-evaluate quarantine and isolation statutes in light of modern realities, to using legislative and policy approaches to manage the governmental response to epidemics. He continues to be at the forefront of emerging public health issues, including the recently-declared emergency for opioid addiction in Maryland, the impact of civil unrest and gun safety on public health, and issues arising from novel emerging infectious and vector borne diseases, such as the Zika virus.

Since the Center opened, Professor Greenberger's health and public health work has focused on providing clients with extensive legal expertise on the public health emergency legal landscape. For example, he might be asked by a county government who can implement quarantine and isolation in the event of a severe pandemic influenza; whether the Governor of Maryland has the power to close schools or public offices in a natural disaster; in the event of a bioterrorist attack, what legal protections are in place for citizens who are subject to quarantine orders? After answering questions like these over several years for multiple governmental entities, Greenberger and CHHS embarked on one of the Center's hallmark projects, the Public Health Emergency Preparedness Legal Handbook. Originally drafted in 2010, the handbook outlines key issues, laws, and regulations relevant to emergency public health preparedness and response, with specific focus on state and federal laws and regulations pertaining to a catastrophic health emergency. The handbook was one of the first of its kind nationally, and became the benchmark for such

*U.S. News and World Report* ranked  
Maryland Carey Law's Health Law  
Program #2 in the country for 2017!

#2



guides. Since that time, Maryland and the U.S. have learned important lessons in public health from responding to pandemic influenzas, Ebola, and the Zika virus. Now, CHHS is working with the Maryland Department of Health and Mental Hygiene to update the handbook with the legal and policy developments that have occurred since 2010, including changes to Maryland law as well as to federal regulations. These laws include changes to emergency preparedness requirements for health care facilities that accept Medicare and Medicaid patients, and federal quarantine and isolation regulations.



**CHHS Senior Law and Policy Analyst Eric Oddo, delivering a tabletop exercise**

The legal landscape for public health emergencies doesn't just affect public health or health care workers, however. The recent Ebola outbreak highlighted the interplay between an infectious disease outbreak and government agencies that are not typically associated with health and health care. When Ebola first occurred in the U.S. during the 2014-

**“What makes the work of the Center so great is that it is truly an interprofessional collaboration. We have on our staff JDs with Health Law certificates and MPHs; and we work with our highly regarded Maryland health law faculty, as well as the medical school faculty, the Center for Vaccine Development, and the Cowley Shock Trauma Center—to ensure the most comprehensive breadth of work possible.”**

**- CHHS Founder and Director Professor Michael Greenberger**

2016 epidemic, one of the first clients to call CHHS with questions was a state transportation agency. While the number of cases of Ebola in the U.S. was very few, the limited exposures identified a number of potential preparedness gaps, particularly for those in the transportation sector. The National Academies of Science Transportation Research Board (TRB) contracted with CHHS to determine whether transit agencies were prepared for an infectious disease outbreak and whether they had adequate procedures in place that take into account legal obligations that may affect transit stakeholders' ability to operate or respond in a public health crisis. After an intensive, year-long legal research project, CHHS prepared the report: *Public Transit Emergency Preparedness against Ebola and Other Infectious Diseases: Legal Issues*.

The TRB report includes extensive, nation-wide research and analysis of the transportation and public health

emergency legal landscape, including federal transportation and public health laws, regulations, statutes, and agency policy guidance. CHHS also conducted an extensive, 50-state survey of public health emergency laws to include in the report. CHHS staff personally contacted and surveyed 250 transit agencies across the country about their public health emergency protocols and procedures. The report, available this spring through the Transportation Research Board's [website](#), underscores the importance of Professor Greenberger's work through the Center in providing public health legal expertise across various sectors of government.

A signature service of Professor Greenberger and the Center includes taking its extensive public health emergency knowledge and applying it in planning efforts for state, local, and regional agencies—be it emergency management agencies, public health departments, hospitals, or regional

health coalitions. In the past year alone, the Center has created a number of plans for clients, some of which include:

### Communications

When a health emergency occurs, the ability of stakeholders to effectively communicate and share relevant information is critical. CHHS created a Communications and Information Sharing Plan for a regional health coalition, which details how members will communicate during regional events, and includes a detailed discussion of the various available communications mechanisms.

### Evacuation

The ability of hospitals and other health care facilities to quickly and safely evacuate patients is critical during emergencies—a lesson highlighted by Hurricane Katrina and Superstorm Sandy. CHHS worked closely with Johns Hopkins Hospital to update its hospital evacuation policies and to create an easy-to-read guide and flowchart for hospital personnel to use, which was in turn used to improve a regional coalition's evacuation guidance for hospitals and to help coordinate regional evacuation planning.

### Emerging Infectious Disease

The U.S. experience with Ebola highlighted a number of challenges emerging infectious diseases (EIDs) pose for the U.S. health care system and public health workers. In light of lessons learned, local county health systems across the country began re-evaluating emergency plans, and many realized that new or novel EIDs may require protocols and policies not typically relied on, such as quarantine and isolation, or widespread contact tracing. To comprehensively address these kinds of concerns, two counties requested CHHS' help in creating "Emerging Infectious Disease Plans"



Maryland Carey Law School-based Center for Health and Homeland Security Staff 2017



(EIDPs). CHHS staffers worked with each county's public health stakeholders to provide planning and drafting assistance for their EIDPs. Each plan was designed to serve as a flexible, scalable, adaptable resource for those individuals and teams working to respond to the effects of an EID in the county. CHHS worked with stakeholders to identify planning barriers and considerations unique to emerging infectious disease response. Much of the Center's work, focuses on "boots on the ground" public health response.

For example, in summer and fall of 2016, the U.S. raced to address the

emerging Zika virus outbreak, after locally-acquired cases were reported in Florida and Texas. The response to this virus, which is vector-borne but also sexually-transmittable, highlights how health and public health preparedness and response can cut across many sectors as public health officials worked with environmental health workers and public works to respond with plans that took into account communication and outreach, vector testing, and spraying and vector control. CHHS staffers working in emergency preparedness and public health offices played critical roles in the Zika response, coordinating communication and

outreach with specific populations, such as pregnant women, and working with environmental and public works agencies to coordinate testing and spraying in affected areas. Center staffers also provided expertise through written analysis, and coordinated with key public health officials, like Baltimore City Health Commissioner Leana Wen, to make informational video blogs available. As summer draws near, efforts to quell the spread of Zika are again ramping up, and Professor Greenberger and CHHS staff are prepared.

## RECENT PRESENTATIONS AND PUBLICATIONS FROM PROFESSOR GREENBERGER AND CHHS STAFF

Michael Greenberger, Presenter and Panelist, *Confronting Legal Health Challenges in Disadvantaged Communities* (speaking on legal approaches to the opioid epidemic), Public Health Law Conference, Washington, D.C., September 16, 2016.

Michael Greenberger, Presenter and Panelist, *Zika Global to Local: Addressing the Epidemic from an International and Interprofessional Lens* (speaking on Maryland public health emergency laws and local response efforts), University of Maryland, Baltimore, Maryland, Global Health Symposium, February 15, 2017.

Trudy Henson, Presenter, *Public Health Legal Issues in Transportation—Current Trends*, Transportation Research Board Annual Legal Workshop, Washington, D.C., July 2016.

Christine Gentry and Ray Shin, *Continuity of Operations Planning During a Public Health Emergency: Resource and Volunteer Management*, 2016 Public Health Preparedness Summit, Dallas, Texas, 2016.

Preeti Emrick and Christine Gentry, *Ebola Virus Disease: International Perspective*, DISASTER AND MILITARY MEDICINE (2016).

# MICROBIOTA TRANSPLANT PROJECT UPDATE

Professor Diane Hoffmann is continuing work on her NIAID-funded project, Microbiota Transplantation: Recommendations for a Regulatory Framework, for a third year with an extension to April 2018. The purpose of the project is to study the legal and regulatory aspects of microbiota transplantation (MT). The most common kind of MT is fecal microbiota transplantation (FMT) which the FDA currently allows as a treatment for refractory *Clostridium difficile* infection (CDI), a serious diarrheal disease.

Hoffmann and co-investigators from the University of Maryland Schools of Law, Pharmacy and Medicine hosted the third meeting of the working group convened under the grant on December 12-13, 2016. The working group is composed of approximately 30 experts and stakeholders including scientists, clinicians, patient and professional association advocates, bioethicists, academics, lawyers, and individuals from the biotechnology industries who have an interest in microbiota transplantation or expertise relevant to the project. In addition, representatives

of FDA and NIH were invited to participate in the working group as observers. Information about the project is available on the project [website](#).

In March 2017, Hoffmann and her co-investigators published the first article stemming from the project in the journal *Gut Microbes*. The article, “A proposed definition of microbiota transplantation for regulatory purposes,” notes that there is currently no regulatory definition of MT or FMT, and the broad range of stool and stool-based products being used, or under development, to treat patients calls for the establishment of a definition to help determine which among them should be “labeled” FMT. The paper focused on FMT but the proposed definition was developed to cover other types of MTs being contemplated, including vaginal, skin, nares, and oral. The investigators are currently working on a paper that sets forth a three track regulatory framework for FMT.

As an outgrowth of the project, Professor Hoffmann was asked by

working group member Dr. Gary Wu to join the Strategic Advisory Board for the American Gastroenterological Association Center for Gut Microbiome Research and Education, of which Dr. Wu is a member. In addition, project investigators Hoffmann and Frank Palumbo, a faculty member at the University of Maryland School of Pharmacy, and working group member Colleen Kelly, a gastroenterologist and faculty member at Brown University Alpert School of Medicine, are speaking on June 6 at the upcoming ELSI Congress on “Genomics and Society” co-sponsored by Columbia Medical Center, UConn Health and the Jackson Laboratory. The team will share the legal issues raised by microbiota transplantation and case studies discussed at working group meetings.

Hoffmann and the other investigators are planning a final meeting of the working group in early 2018 to finalize discussion and recommendations to present to NIH and the FDA.





# FRANK PASQUALE SPEAKS AT “NOBEL PRIZE DIALOGUE TOKYO 2017: THE FUTURE OF INTELLIGENCE”

On February 26, Law & Health Care Program professor Frank Pasquale spoke as an invited guest at a unique panel discussion in Tokyo, Japan to explore the challenges and opportunities created by new frontiers of human and artificial intelligence. The event was organized by Nobel Media, part of the Nobel Foundation, as part of its mission to spread knowledge about Nobel Prize-winning achievements and to stimulate interest in science, literature and peace across the globe. The conference brought together key opinion leaders, policy makers, students, and researchers, including Nobel Laureates Jean-Pierre Sauvage (Nobel Prize in Chemistry 2016), Edvard I. Moser (Nobel Prize in Physiology or Medicine 2014), Eric S. Maskin (Prize in Economic Sciences 2007), George F. Smoot (Nobel Prize in Physics 2006), and Susumu Tonegawa (Nobel Prize in Physiology or Medicine 1987). Organizers asked speakers to think about such questions as: What will the future of intelligence be? What challenges do our societies face from science and technology? What sorts of intelligence do we need to meet future challenges?



Professor Frank Pasquale (second from left)

The event can be viewed at this Youtube link: <https://www.youtube.com/nobeldialogue>.

Pasquale was on a panel with Dr. Moser titled “Challenges of Science and Technology.” In his comments, Pasquale talked about his article, “The Algorithmic Self,” which explored the psychological and social consequences of algorithmic assessments of health, employment, and popularity. Pasquale’s invitation to this prestigious event stems from his scholarship about the challenges posed to information law by rapidly changing technology, particularly in the health care, internet, and finance industries. He is a member of the NSF-funded Council for Big Data, Ethics, and Society, and an Affiliate Fellow of Yale Law School’s Information Society Project. He frequently presents on the ethical, legal, and social implications of information technology for attorneys, physicians, and other health professionals. His book *THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION* (Harvard University Press, 2015) develops a social theory regarding how computational intelligence has come to dominate three important parts of American life: reputation, search, and finance.



Professor Pasquale (center) with participants in Taiwanese workshop

A few days after the Nobel Event, Pasquale also led a workshop at Taiwan’s Academia Sinica, one of the leading research institutions in Asia, on predictive analytics and big data in learning health care systems. Pasquale met with some of the leading privacy and big data analysts in Taiwan, in an event that convened attorneys, academics, computer scientists, and social scientists. He also presented a preview of his current book project, *Laws of Robotics*, at National Taiwan University’s law school, focusing on the legal questions raised by medical automation and robotics.

# PROFILE . . . DR. ANITA TARZIAN, NURSE, BIOETHICIST, CRITICAL MEMBER OF THE LAW & HEALTH CARE PROGRAM

One of the lesser known, but possibly most unique, components of Maryland Carey Law's health law program is the Maryland Healthcare Ethics Committee Network (MHECN), a membership organization designed to support and provide educational resources to ethics committees serving health care institutions in the state of Maryland. This critical resource for ethics committees was the brainchild of Law & Health Care Program (L&HCP) director Diane Hoffmann who started the Network in 1992 to address a gap in resources available to ethics committees. Dr. Tarzian is now the program coordinator for the network and takes the lead role in what has become a robust network of ethics committees, bioethicists, health care providers, and others interested in bioethics. Dr. Tarzian is well known in the field of bioethics and a treasure in the L&HCP.

Tarzian began work as a tertiary care nurse in Chicago in 1986. She worked in a surgical oncology unit of a large academic medical center. This position introduced Tarzian to end-of-life situations that presented complex ethical questions that had to be answered by the medical team and families with no ethics committee to provide support and expertise.

In 1990, Tarzian joined the Peace Corps and served for two years in the Dominican Republic



Professor Anita Tarzian

(DR). In the DR, Tarzian observed another way of dealing with death and dying and how that process looks in a country with fewer medical resources. Tarzian felt there had to be a better way to move patients compassionately through medical crises and through the dying process, particularly in countries like the U.S. where high-tech medical interventions and burgeoning specialty services challenged the humanistic nature of how health care is delivered. After serving in the Peace Corps, she enrolled at the University of Maryland School of Nursing (which is part of the UMB downtown campus, across the street from the law school). At the time, the nursing school offered an MS in Intercultural Nursing, which was a perfect landing spot for Tarzian after serving in the Peace Corps. Tarzian completed a combined M.S.-Ph.D. program with a concentration in ethics. She was named the Outstanding Doctoral Graduate of her graduating class.

During her PhD studies, Tarzian worked as a hospice nurse in home-based and inpatient settings. This experience allowed her to understand patients' needs and desires in the dying process, and how to support the loved ones of patients at the end of life. Also while getting her graduate degrees, Tarzian took a class offered by Professor Diane Hoffmann at the law school, called Critical issues in Health Care. The course was open to all professional students on the UMB Campus, i.e., law, medical, nursing, social work, dentistry and social work. Tarzian was a star in the class.

A few years later, in 1998, Hoffmann, a nationally recognized expert in medical decision making at the end of life, received funding from the Greenwall Foundation to evaluate competencies of individuals conducting ethics consults. She asked Anita to work with her on this project. The two have been collaborating closely ever since and jointly running MHECN. In addition to preparing the MHECN newsletter and responding to questions from network members, Tarzian organizes annual workshops for network members and others. The topics are wide-ranging and include Challenges in Organ Donation and Transplantation, Religious, Medical, Ethical and Legal Perspectives on End of Life Issues, and Ethical and Legal Issues in Dementia: Navigating Difficult Decisions.

Hoffmann and Tarzian also work on research projects together on topics critical to ethics committees and end-of-life care advocacy. Most recently, MHECN received funding



from the Maryland Department of Health and Mental Hygiene to evaluate the Maryland Medical Orders for Life-Sustaining Treatment (MOLST) program. This study evaluated how MOLST forms are being used and what impact the MOLST program has had on end-of-life care for Marylanders since the MOLST program went into effect statewide in 2011. A manuscript summarizing the study's results (co-authored by law student Nadia Cheevers) has been accepted for publication in the *Journal of Palliative Medicine*.

In addition to coordinating MHECN, Tarzian is also an Associate Professor at the University of Maryland School of Nursing where she teaches a course in end-of-life care and a research course. She also co-teaches the course Death and Dying: Ethical and Legal Considerations for a Thanatology Certificate Program offered through the University of Maryland Graduate School. Tarzian is also an IRB Co-Chair and Human Subjects Protection Consultant at Chesapeake Research Review, Inc. in Columbia, Maryland.

Although a nurse, Tarzian has been very happy with her role at the law school and faculty and staff with the Law & Health Care Program have enjoyed working with her. Coincidentally,

Tarzian serves on the Maryland Judicial Ethics Committee which provides guidance to Maryland's judicial officials regarding professional ethics. Having worked with lawyers for many years in different capacities, Tarzian is very familiar with the law surrounding medical-decision making and finds that she has a different understanding of the role of lawyers in bioethics than many of her colleagues. There is an impression among some in the bioethics field that lawyers should not be included in the work of the ethics committee because they are seen primarily as hospital counsel and too focused on providing legal advice rather than providing ethics advice and support when making patient-centered decisions. However, that is not Tarzian's experience. She has valued the critical input lawyers make to aligning the decisions of ethics committees to the structure of the law and their ability to be creative problem solvers in a complex regulatory area. Her long-time association with the law school has left her with a very positive impression of lawyers in the field. She is proud of this "biased" view of the legal profession, and is happy to be part of the L&HCP. One memory that stands out is learning about the SCOTUS (Supreme Court of the United States) Blog and following the live feed with law school colleagues

when the Supreme Court was deciding the constitutionality of the Affordable Care Act's individual mandate. A moment she recalls as "priceless."

In addition to her work with MHECN, Tarzian is a member of the Living Legacy Foundation's Ethics Committee, the University of Maryland Medical Center's Ethical Advisory Board, and the American Thoracic Society's Unrepresented Patients Working Group. She has served on various task forces and committees of the American Society for Bioethics & Humanities, which awarded her a Distinguished Service Award in 2011. This Spring, she will serve as "Ethicist in Residence" at her alma mater, Knox College.

In the future she dreams of MHECN forming an ethics consortium comprised of members from various health care ethics committees and trainees who would meet virtually to discuss de-identified cases and share insights and best practices. Even more ambitious is her goal of moving the compassionate, informed decision-making process that ethics committee members undertake into the realm of everyday life. Honing skills and knowledge among citizens to resolve values conflicts more broadly is not a bad goal in these tumultuous times.



## MID-ATLANTIC ETHICS COMMITTEE NEWSLETTER

A Newsletter for Ethics Committee Members in Maryland, The District of Columbia and Virginia  
Published by the Law & Health Care Program, University of Maryland Francis King Carey School of Law and the Maryland Health Care Ethics Committee Network  
Fall 2016

**Inside this issue...**

- Global Budget Revenue and Population Health: Maryland's Response to the New Model Agreement with CMS
- Introducing David Muller, Director of Health Care Ethics, Anne Arundel Medical Center
- My Patient: Reflective Health Blog
- Hopkins Performs First HIV to HIV+ Organ Transplant
- Horizon Foundation Announces Howard County Specialty Program
- Johns Hopkins Update
- NH's Centers of Excellence in Pain Education (CEPPE) Modules
- Case Presentation
- Comments from Ethics Committee Members
- Comments from a Physician Ethics Committee Chair
- Calendar of Events

**GLOBAL BUDGET REVENUE AND POPULATION HEALTH: MARYLAND'S RESPONSE TO THE NEW MODEL AGREEMENT WITH CMS**


Hospitals across the country have been under increasing pressure to cut costs. In Maryland, the Global Budget agreement with CMS has put a spotlight on the state's hospitals which may feel as though they are the subject of significant scrutiny as they make efforts to comply with the agreement. Peter Tarzian is a lawyer who represents hospitals, and other health care organizations on corporate and health care regulatory matters. Here he explains Maryland's new hospital reimbursement agreement with CMS and implications for healthcare services provided both in hospitals and in the community.

**Background**

Maryland is the only state where hospitals are not reimbursed for Medicare covered patients using the capitated (diagnosis-related group) and capitated prospective payment system. The State of Maryland has operated its acute care hospitals under a unique state-wide capitated system (the "state cap") since 1977, under which Medicare paid acute care hospitals a set rate for a rate agency—the Health Services Cost Review Commission (HSCRC)—annual of making payments under traditional Medicare methodology. At around that time, many in Maryland and a few other states were granted by CMS rates. In order to secure the rates, rates at each hospital in Maryland had to be approximately the same for all private Medicare, Medicaid, commercial insurers, private payers and the uninsured (here the term "All Payers"). Each hospital's payment rates were based on historical cost data, the health status of the patient population, and the level of uncompensated care provided to that population. In order to maintain the rates, the state was required to keep the growth in Medicare rates.

*(Cont. on page 2)*

**The Mid-Atlantic Ethics Committee Newsletter** is a publication of the Maryland Health Care Ethics Committee Network, an initiative of the University of Maryland Francis King Carey School of Law & Health Care Program. The Newsletter combines educational articles with timely information about bioethics activities. Each issue includes a feature article, a calendar of upcoming events, and a case presentation and commentary by local experts in bioethics, law, medicine, nursing, or related disciplines.  
*Diana E. Hoffmann, JD, MS, Editor*



## MID-ATLANTIC ETHICS COMMITTEE NEWSLETTER

A Newsletter for Ethics Committee Members in Maryland, The District of Columbia and Virginia  
Published by the Law & Health Care Program, University of Maryland Francis King Carey School of Law and the Maryland Health Care Ethics Committee Network  
Winter 2015

**Inside this issue...**

- Ethical and Legal Issues in a Minor's Rejection of Life-Saving Therapy: The Case of Cassandra C.
- Inaugural Interdisciplinary, Interfaith Medical Ethics Conference
- "Aid-in-Dying" Versus "Assisted Suicide" - The Debate Continues
- Physician Losses Licenses for Assisting Patients to End Their Lives
- Calendar of Events

**ETHICAL AND LEGAL ISSUES IN A MINOR'S REJECTION OF LIFE-SAVING THERAPY: THE CASE OF CASSANDRA C.**

In early January, a media frenzy erupted over the Connecticut Supreme Court's decision to compel a 17-year-old with Hodgkin's lymphoma to undergo cancer treatment against her and her mother's wishes. The young woman, referred to in legal records as Cassandra C., and her mother, had asked that Cassandra be declared a "mature minor," a legal status that would have given her the right to refuse life-saving treatment. The court held that she lacked the maturity to independently reject treatment that would offer her an 85% chance of surviving her disease. Cassandra was subsequently hospitalized against her will and, as she described in a recently published op-ed, "strapped to a bed by [her] wrists and ankles and sedated" as her physicians could not quickly insert the port through which she now receives chemotherapy.

Cassandra C.'s case is a timely reminder of the legal and ethical issues surrounding therapy, including challenging ethical and legal questions. It is tempting to describe the ethical dilemma as a conflict between health care provider duty to respect their patient's autonomy and their duty to promote beneficence. That dilemma, however, obscures the critically important prequestion of whether the minor patient has the capacity to exercise autonomous choice. Respect for autonomy means respecting the choice that competent individuals make based on their distinctive values, preferences, and plans. The doctrine of informed consent stems from the duty to respect autonomy, and it extends to respecting competent patients' informed decisions about life-saving medical care, even when that refusal will result in the patient's death.

*Diana E. Hoffmann, JD, MS, Editor*

**The Mid-Atlantic Ethics Committee Newsletter** is a publication of the Maryland Health Care Ethics Committee Network, an initiative of the University of Maryland Francis King Carey School of Law & Health Care Program. The Newsletter combines educational articles with timely information about bioethics activities. Each issue includes a feature article, a calendar of upcoming events, and a case presentation and commentary by local experts in bioethics, law, medicine, nursing, or related disciplines.  
*Diana E. Hoffmann, JD, MS, Editor*



## MID-ATLANTIC ETHICS COMMITTEE NEWSLETTER

A Newsletter for Ethics Committee Members in Maryland, The District of Columbia and Virginia  
Published by the Law & Health Care Program, University of Maryland Francis King Carey School of Law and the Maryland Health Care Ethics Committee Network  
Spring 2012

**Inside this issue...**

- MHECN Celebrates 20 Years
- MHECN-sponsored Conferences - A Look Back
- The Conflict Matrix Model: An Innovation for Clinical Ethics Committee Management
- Brian Childs, PhD is the new President-Elect for the College of Pastoral Supervision and Psychotherapy
- Case Presentation
- Calendar of Events

**MHECN CELEBRATES 20 YEARS**

It's hard to believe 20 years have passed since the first issue of this Newsletter was published. There were several forces coalescing then that fostered the birth of the Maryland Health Care Ethics Committee Network (initially called the "Maryland Institutional Ethics Committee Resource Network"), and the inaugural issue of this Newsletter. The following factors included in that first issue underpin the focus on ethical decision-making and related legislation:

- On March 10, 1992, a Maryland Capital Court issued the state's first judicial opinion and case involving termination of life support. The case involved whether to withdraw artificial nutrition and hydration from Ronald Mack, a 31-year-old man who had been in a permanent vegetative state for over eight years. Clear and convincing evidence was established as the appropriate evidentiary standard for terminating life support. The case was appealed to the Maryland Court of Appeals, an initiative of the University of Maryland Francis King Carey School of Law & Health Care Program. The Newsletter combines educational articles with timely information about bioethics activities. Each issue includes a feature article, a calendar of upcoming events, and a case presentation and commentary by local experts in bioethics, law, medicine, nursing, or related disciplines.  
*Diana E. Hoffmann, JD, MS, Editor*
- The federal Patient Self-Determination Act, signed by President Clinton, required by implementation of the Patient Self-Determination Act.
- The D.C. Health Care Decisions Act was amended.
- Maryland legislation on durable powers of attorney for health care and on guardianship, but plans were underway to deal comprehensively.

Back in 1992, the field of bioethics had been evolving over the prior three decades, spurred by interest in medical technology, such as kidney dialysis, cardiac pacemakers, resuscitation, organ transplantation, artificial reproductive techniques, and genetics. The most fundamental questions about life and death, quality of life, and concerns about rising health care costs and the allocation of health care resources. Early deliberations about the ethics of these medical interventions were dominated by physicians and scientists (Levin, 1993). The bioethics movement introduced the perspectives of theologians, philosophers, nurses, psychologists, social workers, lawyers, and others into these discussions to broaden the scope and depth of reflection and analysis. At times, this produced tension between clinicians who viewed "do no harm" as the bedside, "renewal who sought to push the technological envelope of progress and not be hampered

© 2016 University of Maryland Francis King Carey School of Law

Cont. on page 2

© 2012 University of Maryland Francis King Carey School of Law

Cont. on page 2

Law & Health Care Program  
Spring Newsletter 2017 Pg 9

# STUDYING THE ZIKA PANDEMIC FROM GLOBAL AND LOCAL PERSPECTIVES



On February 15, the Law & Health Care Program (L&HCP) and the University of Maryland Baltimore Center for Global Education Initiatives held a campus-wide symposium during which legal and medical experts from the U.S. and Costa Rica described the many faces of the emerging Zika virus. The symposium, “Zika Global to Local: Addressing the Epidemic from an International and Interprofessional Lens,” looked at the virus that is moving deeper into North America and how different sectors in the U.S. are mobilizing to stem the spread of the virus and limit its serious side effects. The panelists were L&HCP professors Leslie Meltzer Henry and Michael Greenberger, University of Maryland School of Medicine faculty members Jon Mark Hirshon and Kathleen Neuzil and the Ambassador from Costa Rica to the United States, the Honorable Román Macaya Hayes.

The Zika virus hit South and Central America hard in 2016 causing those countries to develop

expertise in pandemic response earlier than countries in North America. As Zika moves northward and becomes endemic in U.S. communities, how the US addresses the virus will be greatly informed by the experience of countries in Latin American where the virus first emerged. To that end, the L&HCP was honored to have the Ambassador

from Costa Rica to the U.S., Dr. Román Macaya Hayes, open the symposium and share Costa Rica’s experience with the virus.

The Ambassador was a perfect spokesman for Costa Rica’s pandemic response efforts because, in addition to being a diplomat, he is a chemist and biochemist by training and



Symposium panelists with Ambassador Román Macaya Hayes (fourth from left)



has led R&D teams in the fields of biotechnology and biomedical research in the past. Ambassador Macaya described the country's immediate and targeted approach to surveillance, detection and treatment when Zika was first identified in the country. Because Costa Rica has a nearly universal health care system, public health authorities were able to quickly identify and treat individuals who came down with the virus. Those individuals were monitored closely and treated. Education campaigns were initiated early in the emergence of the virus and were particularly directed to pregnant women given the risk of the disease to unborn children and the potential for serious congenital malformations such as microcephaly. In addition, all pregnant women who needed them were given window and door screens by the government to prevent mosquitos entering their homes. Now that the virus has waned, the Ambassador reported that only two infants have been born with microcephaly linked to the virus. Participants at the conference were particularly struck by the value of a public health system and a unified medical record system to quickly address a pandemic illness.

A number of University of Maryland Baltimore faculty members are using their expertise to develop and refine the legal, medical and regulatory tools needed to face a new epidemic. Dr. Jon Mark Hirshon, a Professor in the Department of Emergency Medicine and in the Department of Epidemiology and Public Health at the University of Maryland School of Medicine, described the clinical and epidemiological characteristics of the Zika virus. Dr. Hirshon recently published "Zika Virus: Critical Information for Emergency Providers" with colleagues and, as a Board Member of the American College of Emergency Physicians, is working on the organization's guidelines for the virus. Dr. Hirshon described how, for

most people, Zika is not harmful but, as noted above, can cause damage to infants in utero. How Zika will spread through the US is likely to be similar to the spread of West Nile virus which is in the same flaviviridae family of mosquito-borne arboviruses. He described how the West Nile virus has, in some ways, prepared us to respond to the Zika virus.

Dr. Kathleen Neuzil, Director of the Center for Vaccine Development (CVD) at University of Maryland School of Medicine, explained that CVD was chosen as one of three National Institute for Allergy and Infectious Diseases (NIAID) study sites for a human safety trial of a new Zika vaccine. The early-stage study will evaluate the experimental vaccine's safety and ability to generate an immune system response in participants. Neuzil explained that existing vaccines for other flaviviruses serve as models for a possible Zika vaccine. Several vaccines are under investigation. Two Phase 1 trials of DNA-based vaccines are

underway. A Phase 1 study of a Zika purified inactivated virion will start soon – this is a vaccine similar to vaccines licensed for the Japanese encephalitis virus. Finally, a live attenuated vaccine (LAV) is under development but not in trials yet. An LAV is currently available for Dengue fever, which is similar to Zika. In sum, there are a number of possible vaccine approaches in the preclinical and clinical study stage, but nothing likely to be available in the next few years. On another note, Neuzil noted that a vaccine designed to treat sexual and intrauterine infection must be safe in children. She explained that the childhood measles-mumps-rubella vaccine ended the 1964-65 U.S. rubella epidemic that, prior to the vaccine, caused 11,000 miscarriages, 2100 newborn deaths, 20,000 babies born with congenital rubella syndrome.

L&HCP Professor Leslie Meltzer Henry, who is on the faculty at MD Carey Law and a core faculty member at the Johns Hopkins Berman Institute

---

L&HCP Director Diane Hoffmann and Professor Leslie Meltzer Henry (from left to right)



of Bioethics, spoke next about the Zika virus and women of reproductive age. In the last several years, Professor Henry has been working intensively as a co-investigator with faculty at the Berman Institute on two projects relating to the ethical conduct of medical research. One project, called PHASES (Pregnancy & HIV/AIDS: Seeking Equitable Study), is looking at conducting research about HIV treatment and prevention during pregnancy and the other is a Wellcome Trust project to develop ethical and legal guidance for conducting research with pregnant women during public health emergencies, like the Zika crisis, where there is an urgent need to attend to the health needs of pregnant women and their offspring.

In her presentation at the Zika symposium, Meltzer compared the advice given by public health officials in Latin America to women of reproductive age versus the lived

reality of these women. In particular, many public health officials have recommended women delay pregnancy for long periods of time to avoid exposing unborn children to the virus. However, in Latin America, where 52% of pregnancies are unplanned and access to contraceptives may be limited, delaying pregnancy is not an option for many women. She also discussed a critical problem in vaccine research – reluctance to enroll pregnant women in clinical trials even when the vaccine is generally considered safe or when the vaccine could prevent a disease that causes harm to pregnant women or their babies. Henry argued that additional research is necessary to determine what research requires participation of pregnant women and what the barriers are to conducting such research in certain target countries.

Rounding out the discussion, Professor Michael Greenberger, a professor at

Maryland Carey Law and Director of the University of Maryland Center for Health and Homeland Security (CHHS) (see story, p. 1) spoke about the law surrounding public health emergencies, particularly disease surveillance, quarantine and isolation. Having served as an expert advisor to governments during prior epidemics (notably Ebola and H1N1), Professor Greenberger shared his conclusion that the most effective way to mobilize American municipalities and citizens during an epidemic is education and leadership rather than the force of law. Whereas Ambassador Macaya stated that, if a safe Zika vaccine become available, it would be required in Costa Rica, Greenberger noted that such an approach would not work in the U.S. where coercion is not the most effective way to mobilize the population.



Dr. Jody Olsen (second from left), Co-Director of the UMB Center for Global Education Initiatives, poses with symposium guests



Panelist Dr. Jon Mark Hirshon



# Maryland Carey Law Wins First Place in Sixth Annual Health Law Regulatory and Compliance Competition



MD Carey Law students Danielle Smith, Ishan Dasgupta, and Mike Pardoe with coach Samantha Collado '16 (coach Alexandria Montanio '15 is not pictured)

More than 30 students from 11 law schools competed in the Sixth Annual Health Law Regulatory and Compliance Competition on Saturday, March 4, founded and hosted by the law school's Law and Health Care Program. The team from Maryland Carey law took first place honors with New York University Law School placing 2nd and Georgia State Law School placing 3rd. Working in teams of two or three, the students had 90 minutes to analyze a hypothetical fact pattern which they were reading for the first time and then present findings and recommendations to a panel of practicing regulatory and compliance attorneys. Thirty-three lawyers from FDA, HHS, and the nation's most prominent health and life sciences law firms participated as judges.

This year's competition focused on the FDA drug approval process and bioethical research issues. In previous years, the focus has been on healthcare fraud and abuse, hospitals, payers, the challenges associated with new clinically integrated care models and FDA-regulated clinical trials and associated compliance issues.

"We are extremely proud of our MD Carey Law students' victory this year," said Professor Diane Hoffmann, longtime director of the school's nationally ranked Law and Health Care Program. "But given the rigor of this competition, all the student teams demonstrated a winning mastery of incredibly complex legal and regulatory issues. The competition is a terrific opportunity for law students to gain hands-on

experience and superb insights from seasoned professionals. We're thrilled at the Competition's growth. Teams are coming from as far away as the west coast to compete."

After the competition, James Valentine '14, an associate at Hyman, Phelps & McNamara and original organizer of the Competition, provided the gathered competitors and judges with a history of the Competition and an explanation of why he and Abraham Gitterman '13, an associate in the FDA and Healthcare Practice Group at Arnold & Porter, worked with Hoffmann to create the event in 2012.

To conclude the award ceremony, Amy Comstock Rick, Executive



Director of the Food and Drug Law Institute (FDLI) addressed the participants during the celebration luncheon sponsored by Baker Donelson. Ms. Rick spoke to the skill level of the law students in the competition and the value these young attorneys will bring to the critically important field of health care compliance. She

described how her experience at FDLI and in prior positions as the Chief Executive Officer of the Parkinson's Action Network (PAN) and President of the Coalition for the Advancement of Medical Research helped her understand the critical role that attorneys can play in developing and shaping the structure of the health care system.

Ms. Rick also announced the prizes that FDLI would present to the winners of the competition.

The competition was supported by Baker Donelson, Arnold & Porter, Hyman, Phelps, McNamara, Nelson Mullins, and the American Health Lawyers Association.



New York University School of Law Team



Georgia State University College of Law Team



---

Professor Frank Palumbo, Andrea Chamblee (Judge) L&HCP Director Diane Hoffmann, James Valentine (Organizer) & Serra Schlanger(Judge) (from left to right)



# 2017 STUART ROME LECTURE: APPIFICATION TO ARTIFICIAL INTELLIGENCE AND HEALTHCARE'S NEW IRON TRIANGLE



Professor Nicolas Terry

On April 6, Professor Nicolas P. Terry, Hall Render Professor of Law and Executive Director of the William S. and Christine S. Hall Center for Law and Health at Indiana University Robert H. McKinney School of Law presented the annual Stuart Rome Lecture at University of Maryland Carey School of Law. The talk, “Appification to AI and Healthcare’s New Iron Triangle,” focused on the intricacy of the impact that advanced information technologies will have on healthcare stakeholders in the future. He predicted that the use of these technologies in health care will grow on several fronts including the use of patient-facing technologies such as medical apps and also next generation technologies such as robotics and artificial intelligence (AI). Professor Terry noted that “health care policy choices in this ‘second machine age’ will possess a degree of complexity that will no longer be reducible (if they ever were) to policy binaries.” He urged the audience, particularly, students of health law and policy, to consider how this level of complexity will impact the foundational approach to discussing health care law and policy – the “iron triangle” of access, quality, and cost containment. In his lecture, Terry suggested that in the near future, a more appropriate way to consider competing priorities in the health care system would be a triangle of automation, quality/safety and empathy.

A link to the Rome Lecture is <http://www.law.umaryland.edu/rome2017>.

The Stuart Rome Lecture was established by his family and friends to celebrate Stuart Rome’s life and work as an attorney, community activist, art patron and humanitarian, and is supported by the Stuart Rome Lecture Fund.

Professor Terry’s talk preceded an invitation-only meeting on April 7 Medical Automation & Robotics Law & Policy Roundtable hosted by L&HCP Professor Frank Pasquale. The roundtable, which will be described in greater detail in the next newsletter, focused on such critical questions as:

- What are best practices for assuring privacy and data security when innovations like cloud robotics could lead to constant real-time monitoring of patients?
- Are robotically-assisted surgeons attaining better outcomes yet? Are factors like recovery time and surgeon satisfaction adequately accounted for in outcomes measures? Could policy change better optimize the use of robotics in surgery? and
- What is the potential for data-driven health care to curb or exacerbate health disparities?



UNIVERSITY of MARYLAND  
FRANCIS KING CAREY  
SCHOOL OF LAW

LAW & HEALTH CARE PROGRAM

500 West Baltimore Street  
Baltimore, MD 21201  
[www.law.umaryland.edu/healthlaw](http://www.law.umaryland.edu/healthlaw)

*Comments and letters should be  
forwarded to the above address.*



## LEGAL RESOURCE CENTER CELEBRATES 15 YEARS OF SERVICE

The Legal Resource Center for Public Health Policy (LRC) at the University of Maryland Carey School of Law was established in 2001 to provide pro bono technical legal assistance on a wide-range of public health issues, including tobacco regulation, injury prevention, to state and local governments, legislators, community organizations, health advocacy groups, and Maryland residents. Directed by L&HCP faculty member Kathleen Hoke, the LRC is a grant-funded legal center that receives primary support from the U.S. Centers for Disease Control and Prevention and the Maryland Department of Health and Mental Hygiene (DHMH). In addition, LRC works closely with state agencies such as the Office of the Comptroller and the Office of the Attorney General, as well as

members of the Maryland General Assembly. In its 15 years of service, the LRC has served as an expert resource center on tobacco control. On May 11, the LRC and DHMH are sponsoring a conference called Navigating the Changing Landscape: The Future of Tobacco Control in Maryland. The conference will focus on engaging communities around tobacco control, licensing and litigation issues, Medicaid coverage for cessation, smoke free housing, and advocacy efforts at the state and federal level.