

LAW & HEALTH CARE PROGRAM



UNIVERSITY of MARYLAND
FRANCIS KING CAREY
SCHOOL OF LAW

FROM THE DIRECTOR

This issue of the L&HCP Newsletter highlights the excellent work of faculty, students and graduates on a wide range of projects. Our cover story focuses on recent work by Prof. Amanda Pustilnik and colleagues to advocate for changes to the assessment of pain in the Social Security disability determination process, building on Pustilnik's longstanding interest in the intersection of the law and chronic pain. We also feature several of our students and graduates who have been able to take advantage of the law school's Business Law Fellowship program to gain valuable experience in healthcare settings and launch their careers as health lawyers.

—*Diane Hoffmann*

PROFESSOR AMANDA PUSTILNIK'S SCHOLARSHIP ON PAIN INFORMS EMERGING POLICIES ON PAIN AND DISABILITY

Chronic pain, defined as pain lasting more than 3 months, is one of the most common health conditions in the United States, affecting approximately 1 in 5 adults.¹ High-impact chronic pain (i.e. pain that limits daily activities) has an estimated prevalence of 8% among American adults.¹ Despite its prevalence and significant impact on the U.S. economy and healthcare system, chronic pain is not widely considered to be a major health problem among the general public.² The lack of tools to measure pain may contribute to the public not viewing chronic pain as a significant issue.

The role of neuroscience in measuring pain has been a longstanding focus of Professor Amanda Pustilnik's scholarship. Her scholarship has examined the use of neuroimaging technologies to measure pain in the legal context, highlighting the limitations of such technologies in providing accurate assessments of individual pain experience.

In 2014, along with Prof. David Seminowicz at the University of Maryland School of Dentistry, Pustilnik organized a symposium at the

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ADDRESSING THE ROLE OF PAIN IN DISABILITY DETERMINATIONS, CONT.

law school, “Imaging the Brain, Changing Minds: Chronic Pain Neuroimaging and the Law,” that brought together legal academics, pain neuroimaging researchers, and policy makers and judges to discuss the latest developments in the field of neuroimaging with regard to chronic pain. The roundtable resulted in a dedicated issue of the *Journal of Health Care Law and Policy* (Volume 18, No. 2, 2015).

Since 2015, Pustilnik has continued her research and scholarship in this area. Her collaborations with scientists on brain imaging of pain led to her recent work on opioids on behalf of the Aspen Institute resulting in a book chapter on “The Law’s Responses to the Opioid Epidemic: Legal Solutions to a Unique Public Health, Criminal Law, and Market-Related Crisis” in *Confronting our Nation’s Opioid Crisis: a Report of the Aspen Health Strategy Group*, (2017). In 2017, she also contributed to a series of articles on brain imaging and chronic pain published in *Nature Reviews Neurology* and *Harvard Review of Psychiatry*.

Recently, Professor Pustilnik was able to turn her scholarship into practical application. In collaboration with colleagues from the Center for Law, Brain, and Behavior at Massachusetts General Hospital, where she holds an appointment, along with numerous scientists studying pain, she was the lead writer for comments submitted to the Social Security Administration (SSA) regarding the assessment of chronic pain in the disability determination process. Signatories include Law & Health Care Program faculty members Leslie Meltzer Henry and Diane Hoffmann as well as colleagues from the University of Maryland Baltimore Center for

Chronic Pain Research (CACPR) Drs. Susan Dorsey, Joel Greenspan, Richard Traub and David Seminowicz.

As background, in order to qualify for Social Security disability benefits (SSDI), SSA must determine whether applicants are eligible to receive benefits based on their ability to engage in work, the medical severity of their impairments, and functional capacity to engage in work. As part of this assessment, SSA considers the medical evidence supporting the claim of disability as well as the individual’s description of symptoms including pain.

In December 2018, the SSA published an advance notice of proposed rulemaking (ANPRM), “Consideration of Pain in the Disability Determination Process,” and solicited public input to determine whether revisions to the current policy on the evaluation of pain are warranted.



Professor Amanda Pustilnik

As outlined in the ANPRM³, the existing regulations involve a two-stage process for evaluating pain. In the first stage, a determination is made regarding whether there is objective medical evidence of an impairment that could reasonably be expected to cause pain. If this criterion is met, the



Consideration of Pain in the Disability Determination Process

A Proposed Rule by the [Social Security Administration](#) on 12/17/2018



PUBLISHED DOCUMENT		DOCUMENT DETAILS
AGENCY:	Social Security Administration.	Printed version: PDF
ACTION:	Advance notice of proposed rulemaking (ANPRM).	Publication Date: 12/17/2018
SUMMARY:	We are soliciting public input to ensure that the manner in which we consider pain in adult and child disability claims under titles II and XVI of the Social Security Act (Act) remains aligned with contemporary medicine and health care	Agency: Social Security Administration
		Dates: To be sure that we consider your comments, we must receive them no later than February 15, 2019.
		Comments Close: 02/15/2019

claim moves to the second stage of the evaluation process. In the second stage, the intensity and persistence of pain is evaluated based on the evidence in the record.

The Social Security Disability Regulations were drafted in 1984, well before the science regarding chronic pain began to shed light on the underlying mechanisms and features of these conditions.

In the comment, Pustilnik and colleagues discuss the scientific advances in the understanding of chronic pain, supplanting the prior prevailing model that mirrored the acute pain model of an identifiable stimulus resulting in the experience of pain. Current scientific understanding of chronic pain disorder recognizes these pain disorders as independent medical entities that may or may not be related to a physical injury. Researchers now recognize that chronic pain disorders involve neurological mechanisms among others (e.g. dysfunctional immune

activation, epigenetic and genetic factors, and the microbiome). The current determination process, however, fails to take these factors into consideration. Prof. Pustilnik and colleagues argue that applications involving chronic pain disorders should take advantage of existing diagnostic criteria that can more accurately assess an individual’s chronic pain condition.

Similarly, the comment authors argue that regulatory requirements that pain be proportionate to the injury or disease are also outdated and contrary to current scientific understanding. As they note, the pain experienced by individuals with chronic pain disorders is inherently disproportionate to identifiable factors and often occur in the absence of an identifiable cause. They recommend that language such as “proportionate” and “subjective” be removed from the regulations.

When disability denials are appealed, the claims often end up in the federal district and appellate courts, which

have developed their own standards for evaluating claims involving pain. The commenters note that the U.S. Court of Appeals for the Fifth Circuit and, in some cases, other Circuits have adopted a standard that chronic pain only meets the definition of disability if the pain is “constant, unremitting, and wholly unresponsive to therapeutic treatment.” However, the accepted biomedical understanding is that variability is an inherent characteristic of pain. As a result, the authors argue, this standard favors fraudulent claims. To address this issue, the authors recommend that SSA develop guidance on chronic pain conditions, including key features of chronic pain disorders, to inform examiner and judicial decision-making.

In current practice, agency examiners penalize applicants who engage in moderate exercise and social engagement, citing these activities

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Save the Date
Stuart Rome Lecture
Thursday October 24, 2019

The Law & Health Care Program is pleased to announce that Allison K. Hoffman, Professor of Law at the University of Pennsylvania Law School and a senior fellow at the Leonard Davis Institute of Health Economics, will deliver the 2019 Stuart Rome Lecture on Thursday, October 24, 2019 at 3pm.

Professor Hoffman is an expert on health care law and policy who has written extensively on health insurance regulation, the Affordable Care Act, Medicaid and Medicare, and will discuss “How Economics Fails Health Law.” Registration details will be forthcoming.

The Stuart Rome Lecture was established by his family and friends to celebrate Stuart Rome’s life and work as a health law attorney, community activist, art patron and humanitarian. The annual lecture is designed to reflect his extraordinarily widespread interest and commitments, stimulating and challenging both those who speak and those who listen.



Professor Allison Hoffman

ADDRESSING THE ROLE OF PAIN IN DISABILITY DETERMINATIONS, CONT.

as evidence of lack of disability. These determinations, however, run counter to prevailing treatment recommendations that such activities are beneficial to recovery. Research studies of chronic lower back pain, for example, have found that mild activity such as walking and physical therapy results in better outcomes than medication or surgical approaches. In addition, social isolation is predictive of greater pain intensity, cognitive impairment and poorer outcomes among individuals experiencing pain. The commenters recommend that SSA promulgate guidance to help examiners assess whether an individual’s activity and social interaction is appropriate and supportive of their recovery versus activity that may undermine the veracity of the claim.

In its efforts to determine whether an individual meets statutory definitions of disability, there has been significant emphasis placed on imaging tests such as CT scans, MRIs and X-rays. Pustilnik and colleagues point out that such tests have limited utility in determinations involving chronic pain disorders given the frequent absence of anatomical abnormalities and the current understanding that some of these conditions are disorders of central nervous system sensitization. Imaging tests are of little utility in such cases and may also lead to inappropriate medical procedures that are unlikely to remedy the experience of pain.

The comment authors also caution against the adoption of fMRI- or EEG-based pain measurement devices as standard practice in evaluations, an argument Prof. Pustilnik and colleagues made in a 2017 publication

in *Nature Reviews Neurology*.⁴ As the authors note, there are significant challenges associated with brain-based pain measurement. First, current technologies have only been proved reliable in detecting acute pain. Second, even if the technology advances so that these techniques can be employed to assess chronic pain, pain detection is a limited marker of the overall condition and should not be the primary factor in a disability determination. Third, pain experience varies over time and testing may occur during a period of low pain intensity that does not accurately reflect an individual’s pain experience. The authors also highlight the lack of standardized protocols and established error rates.

Conclusion

Pustilnik’s comments illustrate the benefit that multidisciplinary collaboration can have on advancing chronic pain research and treatment goals. Pustilnik is hopeful that the comments will lead to changes in SSA policy on chronic pain and result in more appropriate determinations about whether an individual should receive SSDI.

References

1. Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1001–1006. DOI: <http://dx.doi.org/10.15585/mmwr.mm6736a2>
2. Research!America. National poll: chronic pain and drug addiction. Available at: <http://www.research-america.org/sites/default/files/uploads/March-2013painaddiction.pdf>. [Accessed January 16, 2019]
3. <https://www.federalregister.gov/documents/2018/12/17/2018-27169/consideration-of-pain-in-the-disability-determination-process>
4. Davis KD, Flor H, Greely HT, Iannetti GD, Mackey S, Ploner M, Pustilnik AC, Tracey I, Treede R, Wager TD. (2017) Brain imaging tests for chronic pain: medical, legal, and ethical issues and recommendations. *Nature Reviews Neurology*. 13, 624-638.

HEALTH LAW STUDENTS FIND SUCCESS IN BUSINESS FELLOWSHIP PROGRAM

From participating in clinics to completing externships, students in Maryland Carey Law's Health Law program have many opportunities to put the legal theories they learn in the classroom into practice. The Business Law Fellowship Program is the latest addition to the list of ways health law students can get hands-on experience in a real-world setting.

The Business Law Fellowship Program exposes students to knowledge, experience, and mentoring that will speed their transition to a position in health law. The program offers summer fellowships for rising third year law students and postgraduate fellowships for new alumni. Both the summer and postgraduate fellowships include a stipend provided by the employer. The fellowship program also benefits

“In addition to gaining exposure to different practice areas such as transactional and employment law, I have learned a tremendous amount about professionalism, working with others on a team and the corporate environment.”

Nana Tufuoh '18
Fellow at UMMS

from the generous support of alumnus Edward Manno Shumsky '73 and his wife Susan D. Kronick.

Healthcare organizations participating in the summer program include FutureCare Health, which operates a network of rehabilitation and skilled nursing facilities, CareFirst BlueCross BlueShield, and LifeBridge Health, a system of hospitals and affiliated programs in Baltimore. In addition, the Office of General Counsel for the University of Maryland Medical System has accepted a postgraduate fellow every year since 2015. In exchange for hosting fellows, partner organizations are able to enhance their teams with dynamic and thoughtful junior talent from the law school.

Megan Arthur '86, Senior Vice President and General Counsel for the University of Maryland Medical System, spoke about the benefits of the program to both the employer and fellow. From the perspective of the employer, she states: “The corporation benefits from talented, innovative [Fellows]. They bring a lot of energy and enthusiasm.” As for the students, Arthur explains, “They have an opportunity to see how a corporate legal department works, and they receive daily guidance on how to actually be an attorney.”

When he first began his legal training, Vincent Andrews '16 thought that he would become a litigator. Through his exposure to health law via the externship program and health law coursework as well as his participation on the Alternative Dispute Resolution team, Andrews discovered that he really enjoyed negotiation and transactional work. When he was



Edward Manno Shumsky '73 and his wife Susan D. Kronick have played a key role in the development of Maryland Carey Law's Business Fellowship Program since its inception and continue to remain involved with the program through their generous support of the summer fellowship placement at FutureCare. Shumsky attributes the professional successes he and Susan enjoyed over the span of about four decades, in part, to a willingness to take risks. “Lawyers tend to be risk averse,” he points out. “But for me the unintended consequences of taking risks at various steps along my career path transformed my professional experience in a positive way.” Shumsky and Kronick see the fellowship program as a way for budding lawyers to consider taking a different approach to advancing their careers. “We wanted to provide a new and different way to think about the value a legal mind can bring to advancing business growth.”

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HEALTH LAW STUDENTS FIND SUCCESS IN BUSINESS FELLOWSHIP PROGRAM, CONT.

selected for the UMMS Fellowship in 2016, he was able to match those interests with a unique professional opportunity.

The fellowship, he notes, provided him with the real world experience, practical knowledge and professional contacts he needed to advance his career. He credits the fellowship with enabling him to obtain his current position as Associate Counsel at University of Maryland Faculty Physicians, Inc., the physician practice arm of the University of Maryland School of Medicine. "Healthcare is a complex, highly regulated industry. I would not have been able to obtain the position I currently hold had it not been for the experience I gained and the relationships I formed while a fellow at UMMS," notes Andrews.

Nana Tufuoh '18, currently working as a Fellow at the University of Maryland Medical System, describes the fellowship as both rewarding and challenging. "In addition to gaining exposure to different practice areas such as transactional and employment law, I have learned a tremendous amount about professionalism,



Nana Tufuoh '18

working with others on a team and the corporate environment."

2L Lauren Petrin spent the summer of 2018 at LifeBridge Health's Office of General Counsel. Reflecting on her experience, she says, "My role at the General Counsel's office involved a lot of contract work, but I also was able to help the Risk Management Director respond to subpoena requests and sit in on compliance meetings with the hospital's Chief Compliance Officer."

Early Career Boost

Students participating in the Business Law Fellowship Program have found themselves in a much better

position moving forward in their careers. Assistant Dean for Career Development, Dana Morris, touted the benefits of the Program to students, "As Business Fellows, students get a chance to delve into areas of law and a range of business issues that are new to them." Working so closely with established and highly experienced attorneys offers one-of-a-kind experience according to Morris. "Without that kind of exposure and mentorship, fellows would not otherwise be able to gain such a deep experience in such a short time."

That has been Petrin's experience as well: "Attorneys at places I applied to after working at LifeBridge Health were very interested to hear about my experience there, and I believe it was a big factor in getting placements since then. The General Counsel's office was very approachable and everyone was eager to help me learn and took time out of their own days to do so. I would recommend anyone with an interest in health law take the opportunity to work in a General Counsel's office." The Business Fellowship provides such an opportunity.

PANEL DISCUSSES THE MULTICITY LITIGATION DEFENDING THE ACA AGAINST THE TRUMP ADMINISTRATION

On October 25, 2018, the Law & Health Care Program hosted "Trump & the ACA: A Panel Discussion on the Multi-City Litigation." The panel featured Andre Davis '78, Solicitor for Baltimore City (and a party to the lawsuit) and former judge at the U.S. Court of Appeals (4th Circuit) Vincent DeMarco, President of the

Maryland Citizen's Health Initiative, and Mark Graber, University System of Maryland Regents Professor. Diane Hoffmann, Director of the Law & Health Care Program, moderated the panel discussion.

Background

On August 2, 2018, a coalition of four cities (Columbus, OH, Cincinnati, OH, Chicago, IL, and Baltimore, MD) and two private citizens filed suit against the Trump administration for actions taken to sabotage the Affordable Care Act (ACA). In the complaint, the plaintiffs argue that the Trump

Administration actions to significantly scale back the ACA constitute violations of the Administrative Procedure Act (APA) as well as a President's constitutional obligation to "take care that the law be faithfully executed."

The suit references the final rule promulgated by the Centers for Medicare and Medicaid Services (CMS) on Benefit and Payment Parameters for 2019 (the "2019 rule") as well as a series of executive actions that, the plaintiffs allege, have resulted in increased health insurance costs and discouraged enrollment. The 2019 rule includes provisions that eliminate notice requirements to individuals regarding eligibility for advance premium tax credits, shift compliance review of insurance plans offered on federal exchanges to the states, and reduce oversight of the enrollment process, among others. The executive actions include orders to expand access to short-term and association health plans that provide much more limited coverage than that required under the ACA, reject or delay state waiver requests, reduce open enrollment periods for the federal exchanges, and decrease funding for advertising and Navigators. The city of Philadelphia joined the suit in late December 2018. In March 2019, the administration responded to the complaint with a motion to dismiss for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted. A ruling on the motion is pending.

Solicitor Davis discussed the city's involvement in the litigation. Vincent DeMarco provided perspective on the impact of the Trump Administration's actions on Maryland residents. Professor Mark Graber discussed the



constitutional arguments, particularly the argument that the Administration's actions violate the Take Care Clause of the U.S. Constitution.

In discussing the origins of the lawsuit, Solicitor Davis credited Democracy Forward, an advocacy organization that tracks Executive Branch actions. Davis, who served as a judge of the U.S. Court of Appeals until September 2017, recalled the ACA cases he presided over as some of the most meaningful of his career. When he became City Solicitor, one of his first priorities was identifying legal challenges that Baltimore was uniquely suited to bring on behalf of its citizens. To that end, he created an Affirmative Litigation Section in the City Law Department, staffed by attorneys who track activity at the national level to identify opportunities to bring justice to Baltimore and its people.

His office has been very active, bringing suits against oil companies for damage to the climate and against pharmaceutical manufacturers related to the opioid crisis litigation. Baltimore has also joined several

amicus briefs filed in cases brought against the Trump Administration and successfully brought suit against the administration after the Department of Health and Human Services attempted to eliminate the fourth and fifth years of funding of a teen pregnancy education grant.

The multi-city suit discussed by the panel outlines numerous attempts by the Trump Administration to undermine the ACA, including decisions not to enforce the individual mandate as well as significant cuts in money for enrollment platforms and outreach activities. Davis remarked, "It is just a remarkable panoply – everywhere [the Administration] saw that it could undermine the policy of the Affordable Care Act to ensure that the largest number of people possible have access to health insurance, they went after it."

Impact on Maryland

Vinny DeMarco provided historical background for the suit, highlighting Maryland's efforts to establish a "Health Care for All" plan in the state. The final legislation included many provisions that were ultimately

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PANEL DISCUSSES THE MULTICITY LITIGATION DEFENDING THE ACA AGAINST THE TRUMP ADMINISTRATION, CONT.

incorporated into the ACA such as the requirement that large employers provide health insurance for their employees, the increase in the maximum age for dependent coverage, and Medicaid expansion.

DeMarco then discussed several actions taken in Maryland to address Trump Administration actions against the ACA. For example, in 2017, the legislature created the Maryland Health Insurance Coverage Protection Commission.

The nineteen-member Commission is comprised of stakeholders including legislators, state agency representatives, health insurance carriers, health care providers, and members of the public. A key focus area for the Commission is premium rates in the individual and small group markets.

Although most Maryland residents obtain insurance through their employers, Medicare, or Medicaid, there are approximately 200,000 Maryland citizens who obtain insurance through the health benefit exchanges created by the ACA. DeMarco presented data on the “Trump effect” that showed premium rates skyrocketing under the current administration.

In another legislative effort to counter ACA changes, the Maryland General Assembly passed House Bill 1795 during the 2018 session, which directed the Maryland Health Benefit Exchange to submit a waiver application to CMS to establish a state reinsurance program. Under the program, the state pays for the healthcare of the highest cost users.

The funding for the program comes from a tax increase on insurers in Maryland. In addition, the state applied for and received a §1332 waiver to receive federal help to establish the program.

The problem with the reinsurance program, DeMarco noted, is that it is a short-term fix. The funding mechanism devised for the program will only provide two to three years of support. DeMarco supports an approach proposed by Stan Dorn at Families USA: the health insurance down payment. The approach essentially uses the state income tax system to replace the federal government’s enforcement of the individual mandate but uses the tax filing and any penalty fees paid as a “down payment” to enroll the uninsured into coverage.

The Lawsuit’s Constitutional Arguments

Professor Graber provided a historical overview of the Take Care Clause and its use in jurisprudence, noting that the dominant understanding of the clause comes from Justice Hugo Black in *Youngstown Sheet & Tube Co. v. Sawyer*. Justice Black writes: “[t]he President’s power... must stem either from an act of Congress or from the Constitution itself... In the framework of our Constitution, the President’s power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker.”

Graber noted that the complaint in this case is largely comprised of arguments asserting violations of the APA, with very little space in the complaint devoted to the Take Care Clause claim. This is due, he noted, to the fact that if the APA argument fails, then

the Take Care Clause claim also fails. Although he acknowledged numerous instances where the court has done complex statutory dances to uphold major presidential decisions, the court has never said that it is okay for the president to fail to uphold the law. Graber also identified an additional argument — that under the Take Care Clause, the President is obligated to interpret the ACA and other statutes in a coherent fashion. He thinks this is indeed a unique argument, noting, “The justices are likely to say that you have to interpret that statute as a whole, not interpret each clause independent of any other, particularly when such interpretations contradict one another.”

Solicitor Davis agreed with Graber’s interpretation of the Take Care Clause argument in the complaint, asserting that there must be constraints on the executive’s ability to sabotage congressional policy choices, particularly in areas that do not involve matters of national security, war powers, or fights against terrorism.

When asked by an audience member what a “win” would look like in this case, Prof. Graber drew comparisons between the multi-city litigation and the abolitionist movement. Abolitionists, he noted, were the first to litigate to lose. In the process, they called attention to the plight of slaves and fugitive slaves and highlighted for the electorate what was happening. For the plaintiffs in the multi-city lawsuit, if the litigation generates sufficient attention to mobilize people to vote for a President and Congress who actually care about healthcare, that would constitute a “win.”

LAW & HEALTH CARE PROGRAM AND BERMAN INSTITUTE OF BIOETHICS TO HOST CHARM CITY COLLOQUIUM ON LAW & BIOETHICS



Jeffrey Khan, Andreas C. Dracopoulos Director and Robert Henry Levi and Ryda Hecht Levi Professor of Bioethics and Public Policy Berman Institute of Bioethics

On September 27, 2019, the Law & Health Care Program will host the inaugural Charm City Colloquium on Law & Bioethics at Maryland Carey Law. The colloquium will be held in collaboration with the Berman Institute of Bioethics at the Johns Hopkins University.

“The Colloquium represents the next chapter in our collaborative relationship with the Berman Institute,” noted L&HCP Director Diane Hoffmann. “After the combined faculty retreat in 2018, there was a lot of enthusiasm for an event like this. We hope that it will become an annual event where leading health law academics and practitioners, academic bioethicists and health providers can explore questions at the intersection of law and bioethics.”



Diane Hoffman, Law and Health Care Program Director and Jacob A. France Professor of Health Care Law

The topic for this year’s Colloquium focuses on the contribution of bioethics to law and policy and the contribution of law to the field of bioethics. Event attendees will explore questions such as the tensions between bioethics and law; how law impacts ethical practice; the willingness of legal institutions (courts, legislatures, agencies) to entertain bioethics arguments; and the types of bioethics arguments (social justice, utilitarian, religious-based) that are effective in different legal settings, among others.

FRANK PASQUALE APPOINTED TO NATIONAL COMMITTEES

U.S. Secretary of Health and Human Services Alex Azar has appointed Professor Frank Pasquale to a four-year term on the National Committee on Vital and Health Statistics (NCVHS), the Department's public advisory body on health data, statistics and national health information policy. In this role, Prof. Pasquale will help to advise the Secretary on issues related to health data, statistics and privacy as well as the implementation of certain provisions of the Health Insurance Portability and Accountability Act (HIPAA). He will also serve on the Privacy and Security Subcommittee, which is responsible for monitoring new issues and challenges related to health information privacy, confidentiality and security and the development of recommendations to the full Committee.

Legal and regulatory approaches to health data and privacy issues have long been a focus of Professor



I am honored to join [the committee], particularly as the health sector addresses vital opportunities in personalized medicine, and great risks thanks to computational advances in data aggregation, breaches, and reidentification.”

Prof. Frank Pasquale



Professor Frank Pasquale

Pasquale's scholarship. He has authored a number of publications advocating for the development of more robust regulatory frameworks to protect individual privacy and prevent the unethical use of data. He is glad to have the chance to develop recommendations based on his research. “The NCVHS has done vital work to advance interoperability, support the access, exchange, and use of electronic health information, and protect patient privacy and the security of medical data,” Pasquale said. “I am honored to join it, particularly as the health sector addresses vital opportunities in personalized medicine, and great risks thanks to computational advances in data aggregation, breaches, and reidentification.”

In addition to the NCVHS appointment, Prof. Pasquale was recently appointed to the Committee on Scientific Freedom and Responsibility (CSFR) of the

American Association for the Advancement of Science (AAAS). The CSFR is charged with the development of principles and procedures to guide AAAS in identifying and addressing issues that affect scientific freedom and responsibility as well as monitoring the actions and policies of governments and private organizations that may restrict scientific freedom.

Among other activities, the Committee is currently working on an AAAS initiative on the ethical, legal and social implications of artificial intelligence. “As we recently saw in the CRISPR realm, there is great danger of scientific research running ahead of ethical principles and regulation,” Pasquale said. Institutions like the AAAS are “designed to broker critical conversations in this area, and to promote anticipatory social research. I am very happy to join the committee.”

PROFESSOR RENA STEINZOR OFFERS COURSE ON FOOD SAFETY REGULATION

Professor Rena Steinzor is a passionate advocate for environmental, health and safety regulation as a tool for protecting the public health. She has written extensively on the interrelationships between federal, state and local governments and industry as they relate to regulatory systems, worker and consumer safety and the environment. She has testified before Congress on these topics on several occasions and founded the Center for Progressive Reform, a think tank comprised of more than 50 member scholars from academic institutions across the United States that provides research, analysis and commentary on a range of issues related to the environment, health and safety.

Steinzor imparts her knowledge to students in a number of courses including administrative law, courses on the regulatory system, as well as a course on food safety regulation. The food safety course provides students with the opportunity to examine the regulatory frameworks (including oversight by USDA and FDA) that govern the production and safety of food and encourages them to identify gaps in the current system and possible approaches to address them. Steinzor has edited, authored or co-authored a number of books on the intersection between law, health and environment including *The People's Agents and the Battle to Protect the American Public: Special Interests, Government, and Threats to Health, Safety, and the Environment* (coauthored with Sidney Shapiro in 2010) and *Mother Earth and Uncle Sam: How Pollution and Hollow Government Hurt Our Kids* (2007), *Rescuing Science from Politics* (edited with Wendy Wagner, 2006), and *A New Progressive Agenda for Public Health and the Environment*



Professor Rena Steinzor

(with co-editor Christopher Schroeder in 2005).

Steinzor said of her motivation to develop the course, “Food safety law is an emerging and rapidly growing field, at the nexus between environmental and public health law. Food is a fulcrum for some of the most important public health issues of our time, including the lack of nutritious food in America’s inner cities, climate change-induced food shortages, and obesity.”

Kyla Kaplan, a second year law student, offered the following reflection about the course and the larger topic of food safety: This semester in Food Safety Regulation we learned about ways that regulations can help to foster positive change in what foods Americans have access to. This course provided an overview of the food regulatory system including the Food, Drug, and Cosmetic Act (FDCA) and the Food Safety Modernization Act (FSMA). The course further delved into issues such as GMOs, labeling, environmental impacts of our food system, socio-economic status and food, and nutrition concerns.

Food is a major component of everyday life. Not only do we need it to survive, but food is part of religion, culture, policies, and basically every

aspect of what makes us human. About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

Food in general is a huge public health issue – there are issues related to access, what food is commercially available to American consumers, as well as issues of food quality and the impact that has on individual health. As Americans, we have one of the highest processed-food diets in the world. We consume excess amounts of sugar, salt, and fat and this is leading to more cases of obesity, heart disease, and other chronic illnesses.

What made this course so interesting and impactful were the group discussions that the class had every week. The course was a forum for people to share their opinions, ask questions, and debate topics when they did not agree. Food as a public health concern is something that impacts everyone, and people can engage in productive conversation about the topic even if they have little background.

A major theme that was repeated throughout the course was the idea that in order to see real change in the way people access and then consume food, there needs to be bottom-up efforts, i.e., there needs to be individuals fostering change at the community level and implementing strong policies that communities want to see. Lawyers can play a significant role in helping to change our food system so that food becomes less of a public health concern.

ALUMNUS JOHN LESSNER '93 INVESTS IN THE NEXT GENERATION OF HEALTH LAWYERS

One of the Law & Health Care Program's greatest strengths is its active and engaged alumni base that includes not only the 600+ graduates who have successfully completed the requirements for the health law certificate but also hundreds of graduates who took advantage of the program's strong health law curriculum prior to the launch of the formal certificate program. John Lessner is one such graduate.

A native Baltimorean, Lessner was working for the Maryland Department of Aging running a housing program for senior citizens when he decided to pursue his law degree in the evening at Maryland Carey Law. While a student, he had the opportunity to take a class with Professor Karen Rothenberg, gained his first exposure to the field of health law, and embarked on a highly successful career as a health lawyer. After graduation in 1993, he was hired to serve as counsel to the Maryland Medicaid Program for the Maryland Office of the Attorney General in the division that represents the then-Department of Health and Mental Hygiene (now Maryland Department of Health). He later became Counsel to the Office of Health Care Quality, the state agency responsible for licensing healthcare facilities throughout the state.

After eight years at the OAG, Lessner went on to work for Ober Kaler (now Baker Donelson), a major health law firm in Baltimore. It was during his tenure at Ober that John began working with Erickson Living on compliance-related issues and was eventually recruited to serve as in-house counsel. Erickson is a developer and manager of continuing care retirement communities, memory care

centers, nursing homes and certified home health agencies.

As his career has advanced, Lessner has maintained close ties with the Law & Health Care Program, mentoring students through the Student Health Law Organization mentor program and serving as a judge in the annual Health Law Regulatory and Compliance Competition.

This year, Lessner and his husband David Bergman have furthered their commitment to the program by establishing the John Lessner and David Bergman Scholarship Endowment, a fund that will provide critical scholarship support to law students interested in studying health law. Bergman is a Professor Emeritus of English at Towson University and has authored or edited over twenty books including poetry, fiction anthologies and criticism. He is currently writing a crime novel set in an assisted living facility.

Lessner's generosity comes as no surprise to his colleagues (and fellow Maryland alumni) Elizabeth Kameen '83 and Wendy Kronmiller '88. The three first met while working at the OAG and began a friendship that continues decades later. Kameen describes Lessner as "an incredibly special person who is gracious and generous. He is committed to the law school and cares about its students." Kronmiller, who now works with Lessner at Erickson Living, echoes Kameen's sentiments. "I appreciate John's thoughtfulness as both my counsel (at Erickson) and my friend. He is a caring and thoughtful lawyer with an immense knowledge of health care law. He truly cares about our residents."

"We are so grateful to John and David for their support of the Law & Health Care Program," remarked L&HCP Director Diane Hoffmann. "The Lessner/Bergman Scholarship will help us continue to recruit the best and brightest students to Maryland Carey Law."



Dawna Cobb, Wendy Kronmiller '88, Sharon Krevor-Weisbaum '87, Liz Kameen '87, John Lessner '93

MARYLAND CAREY LAW HOSTS 8TH ANNUAL HEALTH LAW COMPETITION

On Saturday February 16, the Law & Health Care Program and the Student Health Law Organization at Maryland Carey Law hosted the 8th Annual Health Law Regulatory and Compliance Competition at the law school. More than 25 students from nine law schools competed in the event. A team from Drexel University Kline School of Law took top honors this year followed by the teams from Mitchell Hamline School of Law (2nd place) and Georgia State University College of Law (3rd place).

Working in teams of two or three, the students had 90 minutes to analyze a hypothetical fact pattern and then present findings and recommendations to a panel of practicing regulatory and compliance attorneys. Lawyers from leading health law firms and policy organizations as well as attorneys from federal agencies including the U.S. Food and Drug Administration and the U.S. Department of Health and Human Services participated as judges.

This year's competition focused on the FDA drug approval process and patient safety issues. "The competition closely simulates real world legal practice by giving students the opportunity to analyze a problem and present their findings to their hypothetical client (the panel of judges)," noted Diane Hoffmann, Director of the Law & Health Care Program. "They need to analyze the legal issues from the perspective of the client as well as identify the potential approaches regulatory oversight bodies may take, all under

significant time pressure. Based on the feedback we received from judges, it is clear that these students will be well prepared as they move into practice."

Abe Gitterman '13, founder of the competition and associate in the Life Sciences and Healthcare Regulatory practice of Arnold & Porter, agreed with Hoffmann's assessment. "The fact pattern draws on the latest cases and settlements in food and drug law as well as healthcare regulatory law. These are real-life issues that give student participants a glimpse into actual practice where they must consider the implications from a business perspective. It's not an abstract academic exercise." He added, "I am delighted to see that the competition continues to draw students from across the country eight years after its inception."

Before announcing the competition winners, David Cade '85, Executive Vice President and CEO of the American Health Lawyers Association, delivered a keynote address to attendees during the celebration luncheon. He praised the competitors for taking time away from their studies to learn the "fine art of lawyering" through their participation in the competition. He encouraged students to seek out similar opportunities to strengthen their communication skills, emphasizing the important role that listening to clients plays in success as a lawyer. AHLA, as well as the Food and Drug Law Institute, donated the prizes awarded to the winning teams.



Drexel University Kline School of Law team took top honors at the 8th Annual Health Law Regulatory and Compliance Competition.



Mitchell Hamline School of Law - 2nd place team



Georgia State University - 3rd place team



David Cade '85, Executive Vice President and CEO of the American Health Lawyers Association delivers the keynote address

The competition received generous support from the following organizations:
Premier Sponsor: Baker Donelson
Platinum Sponsors: Arnold & Porter, American Health Lawyers Association
Gold Sponsors: Food and Drug Law Institute

A LEGACY OF HEALTH LAW: HONORING JIM DOHERTY

Jaime Doherty, long-time adjunct faculty member in the Law & Health Care Program, provides many Carey Law students with their first introduction to health law through the Health Care Law & Policy survey course. Currently a principal at Pecore & Doherty, a boutique health law firm based in Columbia, MD, Prof. Doherty has worked as a health lawyer for many years, including positions with the Johns Hopkins Health System, hospital chain Tenet Health Care, as well as New American Health, LLC, a Maryland-based managed care organization.



Jim Doherty Sr.

For Prof. Doherty, health law is a family tradition. His father, James F. Doherty, Sr., was a prominent health law attorney in the Washington, DC area. Sadly, Jim Doherty passed away in December 2018. Here we share a brief remembrance of his remarkable life:
Born in Cincinnati, Ohio, Jim

Doherty attended Catholic University and Georgetown Law School in Washington. Jim joined the U.S. Air Force, serving two tours in Korea and was there for both major Chinese offensives. He received two Bronze Stars for Meritorious Service in a Field of Combat and a Korean Service Medal. Upon returning from the war, Jim attended Georgetown Law School and began his career in labor law, representing carpenters and upholsterers, and Teamsters among others. After representing a group of Teamsters who unsuccessfully attempted to wrest control of the local union from the famed Jimmy Hoffa, he took a job at the U.S. Department of Labor in Washington and then became a Legislative Representative for the AFL-CIO. Having gained a reputation in Washington as a skilled and effective legislative operative, he was hired as the General Counsel of the Committee on Banking and Currency in the U.S. House of Representatives. He participated in drafting and amending a number of significant federal statutes, The Federal Water Pollution Control Act, The Clean Water Act, The Truth in Lending Act, The Federal Housing Act, The Consumer Credit Protection Act and others.

From there, he went on to become Legislative Counsel and later President and CEO of the Group Health Association of America, a national trade group for health

plans. Jim was the principal legislative architect of the Federal Health Maintenance Organization Act of 1973, which stimulated the development of alternative health care delivery systems around the country and increased access to health care and reduced costs for millions of people, and he drafted and lobbied for later amendments that permitted managed care plans to participate in Medicare. He was the Founding President of the American Health Lawyers Association, a national, non-profit educational group of health care attorneys, and he was instrumental in the formation of the National Committee for Quality Assurance, the national managed care accrediting body.



James F. Doherty Jr.

Jaime, who has taught as an adjunct since 1997, dedicated his Health Care Law and Policy class this spring to his father.

L&HCP ALUMNA ANDREA CHAMBLEE ESTABLISHES SCHOLARSHIP IN MEMORY OF HUSBAND

Andrea Chamblee '86, Senior Regulatory Counsel at the U.S. Food and Drug Administration and longtime friend of the Law & Health Care Program, has established a scholarship to support student journalists in memory of her husband, John McNamara. McNamara, a 1983 graduate of the University of Maryland Philip Merrill College of Journalism, was killed in the mass shooting at the offices of the Capitol-Gazette newspaper in June of last year.

The scholarship will honor McNamara's legacy and impact through merit-based scholarships for undergraduate students interested in sports journalism. Donations in any amount are welcome and appreciated. Donations may be made online at bit.ly/JMacScholarship.



Front: Journalism Dean Lucy Danglish, Andrea Chamblee
Back: Donors and Founders Douglas and Mary Donatelli

CALL FOR PAPERS: HOT TOPICS FOR HEALTHCARE IN-HOUSE COUNSEL

On October 11, 2019, the Law & Health Care Program at the University of Maryland Carey School of Law, the American Health Lawyers Association (AHLA), and the American Society for Health Care Risk Management (ASHRM) will cosponsor "Hot Topics for In-House Counsel," a roundtable discussion for in-house counsel at healthcare organizations. The event is intended to provide in-house counsel with an opportunity for informal dialogue on pressing issues facing healthcare organizations and provide the basis for a symposium issue of the *Journal of Health Care Law & Policy*.

The planning committee, comprising Maryland Carey Law graduates with experience serving as general counsel at leading healthcare institutions across the country, has identified the following five topics for discussion:

- 1) discrimination by patients and health care providers;
- 2) the challenges of discharge for vulnerable patients, including the practice of medical repatriation;
- 3) new disclosure issues associated with mergers and acquisitions, e.g., cybersecurity;
- 4) opioid use and prescribing concerns in the ER and for admitted patients;

5) the challenges for health care institutions presented by the expanding access to medical marijuana in many states.

If you are working on an article or are interested in developing a manuscript on one of these topics for possible publication in the law school's *Journal of Health Care Law & Policy*, please contact Diane Hoffmann at dhoffmann@law.umaryland.edu.

If you are interested in exploring ways that you can support the Law & Health Care Program, please contact Shara Boonshaft, Senior Director of Philanthropy, at sboonshaft@law.umaryland.edu



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FRANCIS KING CAREY
SCHOOL OF LAW

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