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Shepard Broad College of Law

NOVA LAW REVIEW

NOVA SOUTHEASTERN UNIVERSITY

2016 Nova Law Review Symposium

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Regulating Innovation in Healthcare: Protecting the Public or Stifling Progress?

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Welcome from the Nova Law Review

On behalf of the Executive Board of the Nova Law Review, welcome to the 2016 Nova Law Review Symposium, "Regulating Innovation in Healthcare: Protecting the Public or Stifling Progress?" This symposium is an occasion for legal professionals, health care professionals, and community activists to come together to discuss the opportunity, legality, advisability, and effects of the healthcare regulation. Topics of discussion will range from new legislation and regulation aimed at achieving health equity, to emerging business models in the healthcare industry, to the impact and risks posed by advancements in technology and developments in research. Additionally, attendees will have the unique opportunity to learn from prominent attorneys and law professors from around the country, including hearing from representatives from the Centers for Medicare & Medicaid Services, Dialysis Patient Citizens, Modernizing Medicine, among many others. Overall, the goal of this event is to provoke conversation and awareness about important issues affecting the healthcare industry that will advance solutions to nationwide problems.

We thank you for attending and hope you enjoy the presentations.

Alison Barbiero

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Shepard Broad College of Law: Nova Southeastern University's College of Law offers a cutting edge, skills-centered academic program in three-year full-time and four-year part-time divisions. With its recently redeveloped clinical programs, every NSU Law student is guaranteed a live-client experience. In-house clinical studies are supplemented by full-time field placement opportunities practicing law in Florida, across the United States, or select locations throughout the globe. To solidify student success after graduation, NSU Law pioneered a curriculum on the business of lawyering through the Global Law Leadership Initiative. NSU Law students have a myriad of curricular opportunities, including a rich, diverse curriculum, concentrations in International Law or Health Law; dual degree programs abroad in Rome, Barcelona, or Prague; dual degree programs at many of NSU's 17 colleges; and much more. For more information, please visit www.law.nova.edu.

Schedule of Events

9:00 – 9:15 am	**Welcome & Introductions**	**Jon Garon**, Dean of NSU College of Law & **Alison Barbiero,** Nova Law Review Editor-in-Chief
9:15 – 10:45 am	**The Search for Health Equity Through Legislation and Regulation** **Moderators:** **Speakers on Panel:**	**Kathy Cerminara,** NSU Professor of Law & **Marilyn Uzdavines,** NSU Assistant Professor of Law **Daniel Dawes,** Executive Director of Health Policy and External Affairs, Morehouse School of Medicine **Renard Murray,** Consortium Administrator for Quality Improvement and Survey and Certifications Operations (CQISCO), Centers for Medicare & Medicaid Services
10:45 – 11:00 am	**Break**	
11:00 – 12:30 pm	**Using Technology in This "Brave New World"** **Moderator:** **Speakers on Panel:**	**Mark Fleisher**, Senior Executive Vice President and General Counsel, Modernizing Medicine **Cason Schmit,** Research Assistant Professor, Texas A&M College of Public Health, *Transitioning from Paper to Digital: State Statutory and Regulatory Frameworks to Address Health Information Technology* **Fazal Khan,** Associate Professor of Law, University of Georgia School of Law*: The 'Uberization' of Healthcare: The Forthcoming Legal Storm Over Mobile Health Technology's Impact on the Medical Profession* **Christopher Kersbergen (NSU JD 2015),** Professor, Keiser University, *Cybersecurity of Medical Devices*
12:30 – 1:30 pm	**Lunch**	

1:30 – 3:00 pm	**Innovations in the Business of Providing Health Care**	
	Moderator:	**Rachele Hendricks-Sturrup**, M.S., M.A., NSU Doctoral Student, College of Health Care Sciences
	Speakers on Panel:	**Jackson Williams,** Director of Government Affairs, Dialysis Patient Citizens, *The Persistence of Opportunistic Business Models in Health Care and a Stronger Role for Insurance Regulators in Containing Health Care Costs* **Stephanie A. Gernant,** Assistant Professor of Pharmacy Practice, NSU College of Pharmacy, *Emerging Business Models: Innovating Partnerships Between Accountable Care Organizations and Pharmacists* **Stacey Tovino,** Lehman Professor of Law and Director, Health Law Program, University of Nevada, Las Vegas William S. Boyd School of Law, *Regulating Grateful Patient Fundraising: Protecting Confidentiality or Stifling Philanthropy?*
3:00 – 3:15 pm	**Break**	
3:15 – 4:45 pm	**Balancing Interests in Research and Development**	
	Moderator:	**Candace Lerman**, NSU Law Student, President, PULSE! Health Law Students Society, Rare Disease Patient Advocate
	Speakers on Panel:	**Katherine Macfarlane,** Associate Professor, University of Idaho College of Law, *Sidelining the Sick: The Flaws of "Patient-Friendly" Biosimilar Legislation* **Ana Santos Rutschman,** Jaharis Faculty Fellow in Health Law and Intellectual Property, DePaul University College of Law, *FDA Fast-Tracking of the Ebola and Zika Vaccines: Lessons from the Intersection of Health and Intellectual Property* **Sai Balasubramanian,** JD MD Student & Strategy Consulting, *Gene Editing Therapy: The Legal Conundrums Behind This Medical Marvel*
4:45 – 5:30 pm	**Reception**	

For Abstracts and Biographies please visit bit.ly/NSULawSymposium

PowerPoint presentations will be uploaded to this site ASAP following the Symposium.

The Search for Healthy Equity Through Legislation and Regulation

Panelist: Daniel Dawes, Executive Director of Health Policy and External Affairs, Morehouse School of Medicine

Daniel E. Dawes, J.D. is a consultant, healthcare attorney and Executive Director of Health Policy & External Affairs at Morehouse School of Medicine. In addition to his executive role, Mr. Dawes is a lecturer of health law and policy at the Satcher Health Leadership Institute and the Department of Community Health and Preventive Medicine. His extensive background in health policy, especially policies impacting health equity and the elimination of health disparities has allowed him to be a widely sought after expert by local, state and federal policymakers as well as by leading academic institutions, associations, community-based organizations, and companies. He is highly respected for his capacity to achieve sound policy changes in a nonpartisan and collaborative manner. During the negotiations around health reform, he organized the National Working Group on Health Disparities and Health Reform, a working group of more than 300 national organizations and coalitions that worked to ensure that the health reform law included health equity provisions to reduce disparities in health status and health care. He is a frequent speaker and author of several publications on health reform and health equity. Mr. Dawes serves as the Principal Investigator, working closely with the NRC program director, staff, and consultants to ensure successful implementation of the project.

The Search for Healthy Equity Through Legislation and Regulation

Panelist: Dr. Renard Murray, Consortium Administrator for Quality Improvement and Survey and Certifications Operations (CQISCO), Centers for Medicare & Medicaid Services

As CQISCO Consortium Administrator, **Dr. Renard Murray** has field oversight of CMS' clinical quality and survey and certification missions across the United States and its territories, overseeing facilities ranging from the U.S. Virgin Islands in the Caribbean to the Marianas Islands in the Western Pacific.

As recently as July of 2009, Murray was named the Regional Administrator for the Centers for Medicare & Medicaid Services - Atlanta and Dallas Regional Offices. In that position, Murray was responsible for External Affairs and served as the CMS spokesman for the 13 states in the two regions. The states in the Atlanta region, the largest CMS region in the nation, are Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee. Five states, Arkansas, Louisiana, New Mexico, Oklahoma and Texas make up the Dallas region that was also under Murray's watch. Combined, these two regions contain the largest number of Medicare beneficiaries in the U.S.

Murray previously served as Acting Regional Administrator for the CMS Regional Offices in Boston and New York. Directly before his return to Atlanta in 2008, Murray was the Special Assistant to the CMS Chief Operating Officer in Baltimore, Md. In his early days at CMS, Murray served as the Associate Regional Administrator responsible for the Regional Office's Medicaid and Children's Health Insurance Program (CHIP) policy branches and the region's Financial Management Operations.

Murray came to the CMS Atlanta Regional Office from the Social Security Administration (SSA) in 1999. At SSA, Murray held the positions of Claims Representative, Operations Supervisor and District Manager.

A native of Ama, La., Renard L. Murray holds a Bachelor of Science degree in Marketing from Xavier University in New Orleans, La., a Master of Arts degree in Management from the University of Phoenix in Kenner, La. and a Doctorate in Management from the University of Phoenix in Phoenix, Ariz.

The Search for Healthy Equity Through Legislation and Regulation

Moderator: Kathy Cerminara, NSU Professor of Law

Professor Kathy Cerminara bridges the medical and legal professions with her work on patients' rights in the end-of-life decision-making arena. She co-authors the nationally known treatise, The Right to Die: The Law of End-of-Life Decisionmaking, and is a reviewer for several medical and medical-legal journals. Her scholarship most recently has focused on the intersection between end-of-life care, palliative care, and health care coverage policy. At the Nova Southeastern University Shepard Broad College of Law, she is a full professor and serves as Director of Faculty Development.

Professor Cerminara teaches Torts, Health Policy, Bioethics & Quality of Care, Administrative Law, Civil Procedure, and other health-law-related courses. She also created and was the initial director of the online Master of Science in Health Law program for graduate students.

Since 2012, she has been a member of the International Scientific Committee for the International Academy of Law & Mental Health, based in Montreal, Canada. In that position, she has co-organized the stream of therapeutic jurisprudence presentations for two of the Academy's bi-annual Congresses: one in Amsterdam in 2013 and one in Vienna in 2015.

Prior to joining the College of Law faculty, Professor Cerminara taught at St. Thomas University School of Law and the University of Miami School of Law, clerked in the Western District of Pennsylvania and the United States Court of Appeals for the Third Circuit, and practiced law with Reed Smith Shaw & McClay in Pittsburgh, Pennsylvania.

Professor Cerminara received her J.D. magna cum laude from the University of Pittsburgh and her LL.M. and J.S.D. from Columbia University. She is an affiliate member of the Health Law and Tort Trial and Insurance sections of The Florida Bar, a retired member of the Pennsylvania Bar, and a member of organizations such as the American Bar Association; the American Society of Law, Medicine & Ethics; the American Health Lawyers Association; and the Florida Bioethics Network.

The Search for Healthy Equity Through Legislation and Regulation

Moderator: Marilyn Ulzdavines, NSU Professor of Law

Professor Marilyn Uzdavines is an Assistant Professor of Law at Nova Southeastern University Shepard Broad College of Law. She primarily teaches in the area of health care practice and regulation. She teaches J.D. courses in Health Care Compliance, Health Care Organizations, Regulations, and Access, Real Estate Transactions, and other health-related courses. She also teaches Pharmaceutical Law, Legal Perspectives in Health Care Ethics, and Regulatory Compliance in the Nova Southeastern University online Master of Science in Health Law program. Her scholarship explores the regulation of developing areas of medical practice. Professor Uzdavines has spoken at numerous national academic conferences throughout the United States, including the Society of American Law Teacher's Conference and the Health Law Professors Conference.

Professor Uzdavines graduated magna cum laude with a bachelor's degree in political science from the University of Florida and magna cum laude with her law degree from the University of Florida Levin College of Law. In law school, she served as Symposium Editor on the Florida Law Review, and was named a member of the Order of the Coif. She also served as a judicial extern to the Honorable Judge Susan Bucklew in the Middle District of Florida. After law school, she joined the international firm of Holland & Knight, LLC in Tampa, Florida where she practiced corporate law. She later opened the firm, Uzdavines Law Group, P.A. in Clearwater, Florida where she practiced transactional law.

Prior to joining the Nova Southeastern University Shepard Broad College of Law faculty, Professor Uzdavines spent one year as a visiting professor at Stetson College of Law. At Nova Southeastern University Shepard Broad College of Law, she has served as faculty co-advisor for the Hispanic Law Student Association and the PULSE! Health Law Student Association. Additionally, she served on the Masters of Science Online Curriculum Task Force and the College of Law's Governance Committee. She is a member of the Florida Bar and a member of the Florida Bar Committee on Diversity and Inclusion.

Using Technology in This "Brave New World"

Panelist: Cason Schmit, Professor, Texas A&M College of Public Health

Transitioning from Paper to Digital: State Statutory and Regulatory Frameworks to Address Health Information Technology

Presentation Abstract: The US health system is in the midst of a digital revolution that has already changed its efficiency, capacity, and function. Health information in all sectors of healthcare and public health systems is created and shared electronically, and the proliferation of health IT supports a myriad of uses of electronic health information (EHI) beyond patient treatment.

All of these various EHI uses are governed by both federal and state laws. The literature primarily discusses the federal legal framework, focusing on important laws such as Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) Act. New research on state legal frameworks comprehensively reviews state legal frameworks that are a significant part of EHI and health IT governance. Knowledge of these state frameworks is critical to understanding the interaction between health IT governance and the development of technologies that support public health functions.

To provide a macroscopic understanding of the state EHI legal environment, the Public Health Law Program (PHLP) at the Centers for Disease Control and Prevention initiated the first study of EHI-related state laws. Among other findings, this study found more than 2,300 state laws relating to nearly 50 different EHI uses. These findings demonstrate state laws' importance in the governance of EHI use and health IT.

The study also provides empirical support for future evaluation of the effect of state laws on the development of health IT as an emerging technology and its potential to augment and enhance public health capacity and function. This presentation will discuss the study's findings and facilitate discussions of their implications for health IT governance and future uses of EHI.

Cason Schmit is a Research Assistant Professor at Texas A&M University, Department of Health Policy and Management where he actively researches the role of law in health systems.

Prior to joining Texas A&M, he worked for the U.S. Centers for Disease Control and Prevention (CDC) Public Health Law Program as an Oak Ridge Institute for Science Education legal fellow (2013-2015) and as a federal contractor (2015-2016). There he worked with public health professionals within CDC centers and offices and state, tribal, local, and territorial partners to promote the use of law as a tool to improve the public's health. His research with CDC focused

on the role of law in health system transformation, including the use of electronic health information to promote public health, state innovation models, pay-for-success initiatives, and pharmacists' vaccination authority.

He is an active member of the State Bar of Arizona. He earned his J.D. from the Sandra Day O'Connor College of Law at Arizona State University. He has certificates in Health Law, Intellectual Property, and Genomics and Biotechnology Law. He earned his Bachelors of Arts with a dual emphasis in Mathematics and Psychology from Willamette University.

Using Technology in This “Brave New World”

Panelist: Fazal Khan, Associate Professor of Law, University of Georgia School of Law

The 'Uberization' of Healthcare: The Forthcoming Legal Storm Over Mobile Health Technology's Impact on the Medical Profession

Presentation Abstract: Smart machines and software algorithms that can find meaningful patterns within oceans of medical data lie at the heart of the “big data” revolution that is poised to transform medical treatment and delivery. “New growth” theorists are generally optimistic about the impact of technology on society and posit that highly skilled workers, including medical professionals, will come out ahead in this scenario as their skill sets will be amplified by such technology and keep them in high demand. In contrast, these theorists predict that jobs that require less skills and training such as driving a taxi or a commercial truck, will almost certainly be replaced by automation in the near future. One influential study by economists Frey and Osborne predicts that highly-trained health professionals such as physicians, surgeons, dentists, and psychologists, have a less than 1% chance of being replaced by automation over the next two decades. While it is accurate that becoming a competent medical professional requires impressive cognitive skills and lengthy training, numerous studies of medical education and training have demonstrated that the acquisition of medical expertise is based on pattern recognition. Medical professionals are highly valued because they can tap into storehouses of information learned through formal training and experience and apply their analytical skills when a familiar clinical pattern is recognized. However, any human task that is based on pattern recognition, no matter how complex, can be reduced to algorithms that smart machines can consistently and inexpensively reproduce.

Dr. Fazal Khan joined Georgia Law in the fall of 2006. Specializing in health law, Khan teaches Health Law & Policy, Bioethics, Public Health Law and International Products Liability.

His current research focuses on several major themes: reform of the American health care system, the effect of globalization on health care and the challenge of regulating emerging biotechnologies. Representative articles and presentations include proposals on: administrative regulations to protect against epigenetic harms (and endocrine disruptors) in consumer products; ethical regulations on human drug trials in developing countries; rethinking public health laws post-9/11 to ensure adequate protection of civil liberties and effective emergency response; the potential dissonance between personal health records and electronic medical records; and ethical safeguards that would allow organ donation from anencephalic infants.

Recent publications include "Preserving Human Potential As Freedom: A Framework For Regulating Epigenetic Harms" (Health Matrix, 2010) and "Ensuring Government Accountability During Public Health Emergencies" (Harvard Law and Policy Review, 2010).

Khan has considerable experience in both legal and medical fields and has been interviewed and called on as an expert by both television and print media on topics ranging from national health care reform and end of life legal issues to public health legal policies.

He earned his bachelor's degree from the University of Chicago and his medical and legal degrees from the Medical Scholars Program at the University of Illinois at Urbana-Champaign.

Using Technology in This "Brave New World"

Panelist: Christopher Kersbergen, Professor, Keiser University

Cybersecurity of Medical Devices

Presentation Abstract: In May of 2015, The Food and Drug Administration (FDA) issued an alert regarding a vulnerability identified with an infusion system that could allow an unauthorized user to control the device and change the dosage the pump delivers. The vulnerability illustrated a potentially fatal flaw in the health care industry. Patient health information is being stolen at an alarming rate and ransomware style attacks on hospitals is increasing every day. The health care industry has become virtually dependent on these networked devices, and individuals with malicious intent have flocked to take advantage of their weak cybersecurity. In response, the FDA has issued guidance for the Postmarket Management of Cybersecurity in Medical Devices. The guidance has been generally well received for its risked based approach to cybersecurity but has serious shortcomings because it does not address risks to patient privacy, calls for manufacturers to join poorly defined Information Sharing and Analysis Organizations (ISAO), and most importantly nothing in the guidance is enforceable.

The guidance fails to address patient privacy because of a lack of clarity in the way it separates the vulnerabilities affecting "essential clinical performance" of medical devices as controlled or uncontrolled. Without clarification, risks that are related to patient privacy could be ignored because they do not affect patient safety. The guidance also suggests manufacturers join and report vulnerabilities to an ISAO but they do not provide guidance or clarification on whether anything disclosed to the organization would be public information. Medical device manufacturers reporting security vulnerabilities that is available to the general public would attract criminal activity. Finally, the guidance is inadequate because it is not enforceable and does not hold manufacturers responsible for unsecured or defective medical devices. The guidance says that manufacturers should inform users and customers that there is a risk, not must. The FDA missed an opportunity to address the serious issue of data breaches affecting patient privacy. Instead it focused on what may happen rather than what is happening and may have given manufacturers an excuse to not address the problem.

Christopher Kersbergen is a professor of Criminal Justice at Keiser University. He received a Juris Doctorate from Nova Southeastern University in 2015 and has a Master's degree in Criminal Justice from Florida International University and a Bachelor's degree in Political Science from Florida Atlantic University. He is currently pursuing a degree in computer science at Florida State University to become eligible for the patent bar.

He was born in Miami, Florida and joined the United States Army after graduating from high school.

He is a combat veteran and worked at the Shepard Broad College of Law Veteran's Clinic his final year of law school. He also volunteers his time helping veterans like himself and is interested in legal issues and research affecting that community.

Using Technology in This “Brave New World”

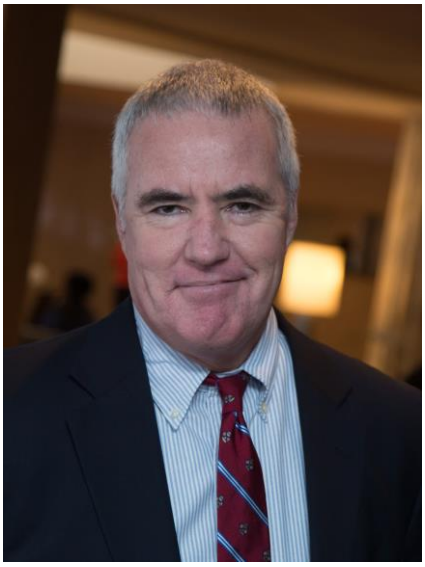
Moderator: Mark Fleisher, senior Executive Vice President and General Counsel, Modernizing Medicine

Mark Fleisher serves as Senior Executive Vice President and General Counsel for Modernizing Medicine in Boca Raton, FL. Mark has over fifteen years of experience of providing legal representation to technology companies. Prior to joining Modernizing Medicine, Mark was a partner with K&L Gates LLP, an international law firm. Prior to K&L Gates, Mark served as Of Counsel with the firm Broad and Cassel and as an associate in the Silicon Valley offices of Latham & Watkins LLP and Wilson Sonsini Goodrich & Rosati, P.C. Mark also previously served as Director, Legal—North America for Avanex Corporation, which was a Silicon Valley based provider of photonic processing solutions.

Innovations in the Business of Providing Health Care

Panelist: Jackson Williams, Director of Government Affairs, Dialysis Patient Citizens

The Persistence of Opportunistic Business Models in Health Care and a Stronger Role for Insurance Regulators in Containing Health Care Costs



Presentation Abstract: While much is heard about new "value-based" payment models for health care, the reality is that old-fashioned business models emphasizing higher unit prices and discrete billable services still prevail, and still succeed in driving up health care costs. Indeed, the spread of global payment models has been cited as an excuse for continued market consolidation by providers.

Ideally, insurers would act as purchasing cooperatives on behalf of consumers, obtaining the lowest possible unit prices from providers. But the most effective tools that purchasers could have—including antitrust and other litigation against providers who act opportunistically—go unused, primarily because of the collective action problem inherent in a multi-payer market.

This paper argues that insurance regulators can catalyze cost containment efforts by encouraging, or mandating, insurers to act vigorously as agents of consumers in obtaining low prices from providers, to include policing provider misconduct in health care markets. The insurance commissioner's regulatory authority can solve the collective action problem by apportioning costs and thereby incentivize cooperation.

The paper identifies three particular problems that perhaps would be best be mitigated through direct regulation of provider prices but could also be addressed through creative use of three tools that insurance regulators possess: Provider market power; excessive prices for "must-have" providers; and surprise medical bills from out-of-network hospital-based providers.

Insurance regulators with rate review authority could withhold permission to increase premiums that reflect provider market power due to inappropriate consolidation, and order insurers to pursue antitrust litigation when prices and HHI exceed a certain threshold.

Regulators could also extend their "catchall authority" to prohibit unfair insurance practices to regulate contracting with providers that ratifiies excessive prices.

Regulators could convene insurers to enforce the quantum meruit doctrine that limits physicians only to UCR-based reimbursement. This could include organizing bellwether trials or organizing insurers to defend collection lawsuits.

Jackson Williams is Director of Government Affairs at Dialysis Patient Citizens. From 2010 to 2013 he worked at the Centers for Medicare and Medicaid Services. Previously he was a health services researcher for the AARP Public Policy Institute and a lobbyist on health policy issues for three non-profit associations. He is an NAIC Funded Consumer Representative, and also was in 2003-2004. He has taught courses in political science and law at the University of Illinois at Chicago, IIT-Kent College of Law, and Pennsylvania State University, Harrisburg.

Innovations in the Business of Providing Health Care

Panelist: Stephanie A. Gernant, Assistant Professor of Pharmacy Practice, NSU College of Pharmacy

Emerging Business Models: Innovating Partnerships Between Accountable Care Organizations and Pharmacists

Presentation Abstract: To identify the barriers, facilitators and legal considerations regarding NSU College of Pharmacy's endeavor to partner with a local Accountable Care Organizations (ACOs).

In 2012 the Patient Protection and Affordable Care Act (ACA) authorized ACO formation to improve safety, costs, and quality of patient care. Pharmacists deliver high quality care in traditional fee for service models, but have been traditionally underutilized within ACOs. To unite healthcare practitioners, academics and ACOs for mutual fiscal, scholarly and patient-care benefits NSU established the ACORN SEED initiative in 2014. Legal considerations, such as HIPAA, medication therapy management contracting, and liability are issues of consideration.

The founding members recount the steps undertaken and overcoming obstacles.

Currently, NSU has partnered with two ACOs representing over 240 primary care practices in South Florida. During the development of ACORN SEED, the founding ACO and academic leadership overcame several challenges related to trust, assuring mutual benefits, and allocating resources.

Despite pharmacists' ability to positively affect the Triple Aim, little has been done to integrate pharmacists in Accountable Care Organizations (ACOs). This description may help other centers of higher healthcare education collaborate with ACOs to develop practice within the ACA's mandates.

Stephanie Gernant is Assistant Professor in NSU's Department of Pharmacy Practice. Her area of research includes transdisciplinary healthcare teams with the focus on the pharmacist's role in accountable primary care settings. Dr. Gernant studied at University of Missouri-Columbia, Ohio State University. She completed her post-graduate residency in an early Pioneer Accountable Care Organization, and fellowship with Purdue University. Her research includes work within practice-based research networks, and she is Coordinator of Research and Grants through NSU's ACO Research Network Services and Education initiative (ACORN SEED).

Innovations in the Business of Providing Health Care

Panelist: Stacey Tovino, Lehman Professor of Law and Director, Health Law Program, University of Nevada, Las Vegas William S. Boyd School of Law

Regulating Grateful Patient Fundraising: Protecting Confidentiality or Stifling Philanthropy?

Presentation Abstract: Grateful patient fundraising is the solicitation of cash or in-kind donations from patients (or family members or friends of patients) who are or may be grateful for the health care given to or received by such patients. Development officers, foundation staff, and other hospital and health system personnel use electronic medical record systems, electronic patient databases, and publicly available records to search for current and former patients with positive health care outcomes who have the apparent means to donate. Once potential grateful patients are identified, fundraising personnel solicit donations in person or by mail, e-mail, or telephone.

The federal Department of Health and Human Services (HHS) has taken a number of different approaches to the use and disclosure of protected health information (PHI) for fundraising purposes. In the November 3, 1999, proposed HIPAA Privacy Rule, HHS would have prohibited covered entities from using or disclosing all PHI for fundraising purposes unless each patient whose information would be used or disclosed gave his or her prior written authorization. See 64 Fed. Reg. 59,918, 60,055 (Nov. 3, 1999). In the December 28, 2000, final HIPAA Privacy Rule, HHS decided to allow covered entities to use and disclose demographic information (including patients' names, addresses, ages, and genders) as well as the dates of health care received for fundraising purposes without prior written authorization; all other information uses and disclosures required patient permission first. See 65 Fed. Reg. 82,462, 82,514, 82,820 (Dec. 28, 2000). In the January 25, 2013, final regulations implementing the Health Information Technology for Economic and Clinical Health (HITECH) Act, HHS changed tack again. That is, HHS decided to allow additional pieces of information, including department of service, treating physician, and health outcomes to be used or disclosed for fundraising purposes without prior patient authorization. See 78 Fed. Reg. 5566, 5700 (Jan. 25, 2013).

In keeping with the theme of this symposium, this presentation will examine the legality, advisability, and effects of the regulation of the use and disclosure of PHI for grateful patient fundraising. Heavy regulation promotes patient autonomy and health information confidentiality at the expense of fundraising. Weak regulation supports health care philanthropy but likely deviates from patients' expectations of privacy.

Professor Stacey A. Tovino is a leading expert in health law, bioethics, and the medical humanities. She has particular expertise in the civil, regulatory, operational, and financial aspects of health law, and she frequently explores issues that lie at the intersection of health law and other fields, such as gaming law, insurance law, and immigration law. Educated as both an attorney and a medical humanist, Professor Tovino publishes her interdisciplinary work in textbooks, casebooks, edited readers, law reviews, medical and science journals, and ethics and humanities journals. Recent law review publications include articles in the Minnesota Law Review, Washington Law Review, Boston College Law Review, Washington and Lee Law Review, Tulane Law Review, Utah Law Review, Florida State University Law Review, Houston Law Review, University of Richmond Law Review, Kentucky Law Journal, Penn State Law Review, Harvard Journal on Legislation, and Harvard Journal of Law and Gender, among many other general and specialty journals.
Professor Tovino is a frequent speaker on the local, national, and international level. She has been invited to guest lecture and present papers on a range of health law, bioethics and medical humanities topics at schools of law, medicine, public health, pharmacy, life sciences, health sciences and public policy, as well as undergraduate and graduate departments of neuroscience, biology, psychology, sociology, philosophy, and humanities across the country.

Prior to joining the faculty at Boyd, Professor Tovino served as Director of the Health Law and Policy Center and Associate Professor of Law at Drake University Law School (2008-10); Assistant Professor of Law at Hamline University School of Law (2006-08); Visiting Assistant Professor, Research Professor, and Adjunct Professor at the University of Houston Law Center (2003-06); and attorney in the Health Industries Group of the Houston office of the international law firm Vinson & Elkins (1997-2003). During her practice, Professor Tovino represented physicians, scientists, allied health professionals, general and special hospitals, academic medical centers, organ procurement organizations, blood banks, AIDS clinics, and nonprofit health care organizations in civil and regulatory matters.

Innovations in the Business of Providing Health Care

Moderator: Rachele Hendricks-Sturrup, M.S., M.A., NSU Doctoral Student, College of Health Care Sciences

Rachele Hendricks-Sturrup holds a Bachelor of Science degree in Biology from Chicago State University, a Master of Science degree in Pharmacology and Toxicology from Michigan State University, and a Master of Art degree in Legal Studies from University of Illinois-Springfield. She is currently pursuing a Doctor of Health Science at Nova Southeastern University. Her work experience involves many years as a biomedical scientist and legal/policy analyst. Her scientific areas of interest include behavioral health, inflammation/oxidative stress, and reproductive malignancies. Rachele is also an active member of the Association for Women in Science, National Association of Science Writers, and Association for Public Policy Analysis and Management.

Balancing Interests in Research and Development

Panelist: Katherine Macfarlane[1], Associate Professor, University of Idaho College of Law

Sidelining the Sick: The Flaws of "Patient-Friendly" Biosimilar Legislation

Presentation Abstract: The most effective medications used to treat chronic debilitating autoimmune diseases such as Rheumatoid Arthritis[2] are also the most expensive, even for those with topshelf insurance. These medications, known as biologics, are "produced by extracting cellular proteins from animals."[3] Enbrel, a biologic produced by Amgen, is the most-prescribed medication for Rheumatoid Arthritis.[4] Amgen's Enbrel sales totaled $4.4 billion in 2014.[5] Anyone that takes Enbrel will not be surprised by the large sums the drug rakes in for its manufacturer; after all, an Enbrel prescription costs nearly $1,200 per month.[6] After fifteen years of market dominance, Amgen is on the legal defensive because Enbrel's market share is at risk. Biosimilars, which replicate biologics with "highly similar, but slightly variant, living organisms or processes,"[7] are poised to enter the American healthcare market. Biosimilars have caused companies like Amgen to panic because they are generally much cheaper than products like Enbrel. Litigation over biosimilars has pitted pharmaceutical giant Sandoz against Amgen in a high-stakes face-off over Sandoz's plans to seek FDA approval for an Enbrel biosimilar.[8] The companies are represented, respectively, by white-shoe law firms Winston Strawn and Sidley Austin. The focus of legal scrutiny in the biologic/biosimilar arena is the Amgen versus Sandoz litigation, the fight over market share, and the biosimilar FDA approval process.[9] These discussions typically examine the Biologic Price Competition and Innovation Act (BPCIA), which established a pathway for the production and sale of biosimilars in the United States in an attempt to reduce the price of biologic drugs.[10] Less coverage has been devoted to state-level battles over biosimilars. States have considered whether biosimilars "should share a generic name with brand-name products, as is the case with traditional, small-molecule drugs, or whether they should be given distinct generic names." If biosimilars receive distinct names, "doctors and patients [may] doubt whether the products are legitimately substitutable," and as a result, biosimilars may be unable to compete with brand-name products like Enbrel.[11] Other state laws have considered imposing "patient consent, recordkeeping, and physician notification requirements to discourage healthcare professionals and consumers from dispensing or consuming biosimilars."[12] Critics of state laws that make biosimilar substitution slow or inefficient argue that "the industry trade associations[, including] the Biotechnology Industry Organization (BIO)" have "waged a vast campaign at the state level to impose burdensome requirements on pharmacists seeking to substitute FDA-approved interchangeable biosimilars for biological products."[13] In California, the site of one of the most closely-followed state attempts at passing biosimilar legislation, the entities lobbying

for the bill's passage included "AbbVie, Amgen, BIO, Genentech and PhRMA."[14] But even when questionable state bills are scrutinized, the problems identified are "political power and insider influence"[15] through which companies like Amgen seek to reduce competition and protect their market share. The state bills are also described as impeding innovation while increasing costs. [16] One consequence of state biosimilar legislation is mentioned as an afterthought: limiting patient access to new medication. This Article seeks to highlight the consequences of restrictive state legislation on patients—those who need medication to walk, breathe, or, sometimes, keep on living. It will describe how everyone but patients has had a voice at the state legislative level, and examine the resultant costs of sidelining the patient experience. Finally, it will compare the patient-focused legislative efforts in states considering Medicaid expansion, arguing that those lobbying efforts should serve as a model for patient participation in healthcare legislation discussions.

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[1] Associate Professor, University of Idaho College of Law, B.A., Northwestern University, J.D., Loyola Law School. The author has suffered from Rheumatoid Arthritis for 35 years, and taken six different biologic medications.

[2] "Rheumatoid arthritis is a nasty disease. Unchecked, the inflammation, destructive changes to joints and dissolution of bone it causes — along with the pain — can lead to disability, lost work time and the need for orthopedic interventions." Carol M. Ostrom, What's behind the whopping price tags on the newest generation of drugs, SEATTLE TIMES, Aug. 17, 2008, http://www.seattletimes.com/seattle-news/health/whats-behind-the-whoppingprice-tags-on-the-newest-generation-of-drugs/.

[3] Brian R. Bouggy, Follow-on Biologics Legislation: Striking A Balance Between Innovation and Affordability, 7 IND. HEALTH L. REV. 367, 368 (2010).

[4] About ENBREL, https://www.enbrel.com/rheumatoid-arthritis/ra-enbrel-treatment-results/.

[5] Carly Helfand, Big question for Pfizer: Will Enbrel's EU biosim bring on the pain?, FIERCEPHARMA, Jan. 19, 2016, http://www.fiercepharma.com/sales-and-marketing/big-question-for-pfizer-will-enbrel-s-eubiosim-bring-on-pain.

[6] Consumer Reports, Treating Rheumatoid Arthritis: Are Biologic Drugs Right for You?, https://www.consumerreports.org/health/resources/pdf/best-buydrugs/BBD_Rheumatoid_Arthritis_Summary.pdf.

[7] Joanna M. Shepherd, Biologic Drugs, Biosimilars, and Barriers to Entry, 25 HEALTH MATRIX 139, 143 (2015).

[8] Sandoz Inc. v. Amgen Inc., 773 F.3d 1274, 1275 (Fed. Cir. 2014).

[9] See, e.g., Kyle Barrett, Implementing the Biologics Price Competition and Innovation Act: Why Legal Principles Justify A Broad Definition of Biosimilarity, 85 S. CAL. L. REV. 1597 (2012); Ryan Timmis, The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme, 13 NW. J. TECH. & INTELL. PROP. 215 (2015).

[10] Id. at 216 (2015).

[11] Public Citizens, Competition Inhibitors: How Biologics Makers Are Leveraging Political Power to Maintain Monopolies and Keep Prices Sky-High, Dec. 18, 2014, http://www.citizen.org/documents/reportbiologics-industry-leverages-political-power-to-maintain-monopolies-and-inflate-prices.pdf.

[12] Sheperd, supra note 7 at 152-53.

[13] Public Citizens, supra note 11.

[14] Id.

[15] Id.

[16] Sheperd, supra note 7 at 155.

Professor Katherine Macfarlane teaches Constitutional Law, Civil Procedure, Civil Rights Litigation and Conflict of Laws at the University of Idaho College of Law. She received her B.A., magna cum laude, from Northwestern University, and her J.D., cum laude, from Loyola Law School, Los Angeles. Preceding her appointment at the College of Law, she taught Civil Rights Litigation, Disability Rights and Legal Writing at LSU's Hebert Law Center. Professor Macfarlane also worked as an Assistant Corporation Counsel in the New York City Law Department's Special Federal Litigation Division, and as an associate at Quinn Emanuel. She clerked for the District of Arizona and for the U.S. Court of Appeals for the Ninth Circuit. Professor Macfarlane is a member of the District of Idaho's Local Rules Committee. She is admitted to practice in New York and California.

In addition to her academic writing, Professor Macfarlane writes frequently about healthcare issues and volunteers as a patient advocate for the Arthritis Foundation. She testified in support of a patient safety bill related to biosimilar medication at the Louisiana Legislature, and participated in a Congressional Arthritis Caucus briefing regarding biosimilars in Washington, D.C. as the panel's sole patient representative. Her healthcare writing has been featured in the Ms. Magazine Blog, The Mighty, Creaky Joints, Intima and BUST.

Balancing Interests in Research and Development

Panelist: Ana Santos Rutschman, Jaharis Faculty Fellow in Health Law and Intellectual Property, DePaul University College of Law

FDA Fast-Tracking of the Ebola and Zika Vaccines: Lessons from the Intersection of Health and Intellectual Property

Presentation Abstract: This presentation explores the recent additions of Ebola and Zika to the FDA's Priority Review Voucher (PRV) Program. The PRV was created in 2007 under the auspices of the Food and Drug Administration (FDA), which issues resalable vouchers that allow the recipient to expedite the review of a new drug, shortening the de facto year-plus period that the FDA takes to conclude the review process to 6 months. Initially, the program was designed to cover neglected tropical diseases, but was subsequently expanded to encompass rare pediatric diseases. Following the 2014-2015 pandemic outbreaks, Ebola and Zika were also added to the program.

Priority review functions as a prize in areas where purely intellectual property-based incentives have traditionally failed to generate substantial innovation: if the drug is approved, priority review buys the recipient lead time over his competitors. That short window of lead time can be valued at as high as US $350 million, the amount fetched by the sale of a rare pediatric disease voucher in 2015. While the voucher system is not exempt from criticism, it remains one of the most prominent mechanisms for creating additional layers of incentives for diseases that fail to attract sufficient R&D under intellectual property-based frameworks.

The 2014-15 Ebola and Zika outbreaks underscored the idea that the intellectual property system is often incapable of offering appropriate incentives to innovation in biopharma. These two recent outbreaks highlight the transactional inefficiencies of "thickets" of intellectual property rights (in the form of protracted patent negotiations) but also offer a case study in a streamlined model that could reduce some of these inefficiencies through regulatory fast-tracking. In particular, the inclusion of Ebola and Zika in the FDA's PRV program might be an indication that the range of diseases eligible for supplemental incentives is poised to grow, and that fast-tracking could soon expand into new domains.

Ana Santos Rutschman is the 2016-2017 Jaharis Faculty Fellow in Health Law and Intellectual Property. Her primary research and teaching interests include intellectual property, health law, incentives theory and innovation policy in the life sciences. For the past two years, Professor Santos Rutschman has been working on the intellectual property-related aspects of the development and licensing of the Ebola and Zika vaccines, having recently consulted for the World Health Organization on this topic. She is currently finishing a related research project mapping and evaluating the impact of intellectual property barriers during recent pandemic

crises, and looking at streamlined processes to expedite the response to future outbreaks. Prior to joining DePaul, Professor Santos Rutschman was the co-director for Global Healthcare Innovation Alliances (GHIA) at Duke University, a visiting professor of intellectual property and an intellectual property consultant.

Balancing Interests in Research and Development

Panelist: Sai Balasubramanian, JD MD Student & Strategy Consulting

Gene Editing Therapy: The Legal Conundrums Behind This Medical Marvel

Presentation Abstract: The proliferation of gene editing therapy has introduced a brand new frontier of medicine, focusing on personalized, patient specific therapy. While the technology and infrastructure are new, the concept finds its roots in basic biology: identify target sequences in an organism's genome, and insert, delete, or replace with engineered, "ideal" DNA. Used correctly, physicians of the future will be able to identify target sequences in the genome of patients that have a predisposition for a genetic ailment, and utilize this therapeutic method to excise or augment these pertinent sequences, potentially deleting the predisposition for the disease itself. While companies such as Editas, Crispr Therapeutics, and Juno Therapeutics continue to develop this technology, many complex legal questions will emerge, centered around issues such as: how to handle margins of error, as DNA editing is not yet a perfect science; what kind of reimbursement methods could a physician expect, as a patient could never objectively know if the therapy preventing his future, currently dormant disease, was even necessary; and perhaps most importantly, how this therapy will be received in light of ever increasing standards of human privacy. Similar technological models such as genome database projects and the practice of selective fertilization may provide some clarity into these questions. The purpose of this paper is to both shed light onto this emerging technology, as well as attempt to bring attention to the larger legal implications of what will surely be a revolutionary field in both law and medicine.

Sai Balasubramanian is an M.D./J.D. dual degree candidate at the Southern Illinois University Schools of Law and Medicine, and is interested in the intersection of healthcare and public policy. His areas of specialty and scholarship include innovation in healthcare, evolving healthcare organizations, and hospital compliance. Sai draws additional experience from his recent work with the US Department of Health and Human Services, where he worked alongside the Office of the General Counsel, and helped the agency's efforts with provider liability and administrative compliance. He also has a strong passion for entrepreneurship and disruptive innovation, interests that developed from his previous career in strategy consulting. He is also an avid writer, and is a regular contributor to The Huffington Post. In his free time, he enjoys traveling and reading.

Balancing Interests in Research and Development

Moderator: Candace Lerman, NSU Law Student, President, PULSE! Health Law Students Society, Rare Disease Patient Advocate

Candace Lerman is a rare disease patient and advocate from Fort Lauderdale, Florida. She is currently a Juris Doctor candidate at Nova Southeastern University with plans to pursue a Doctorate in the College of Pharmacy upon graduation. Candace is the Florida Director of the Rare Disease United Foundation and blogs about healthcare issues at RareCandace.com.