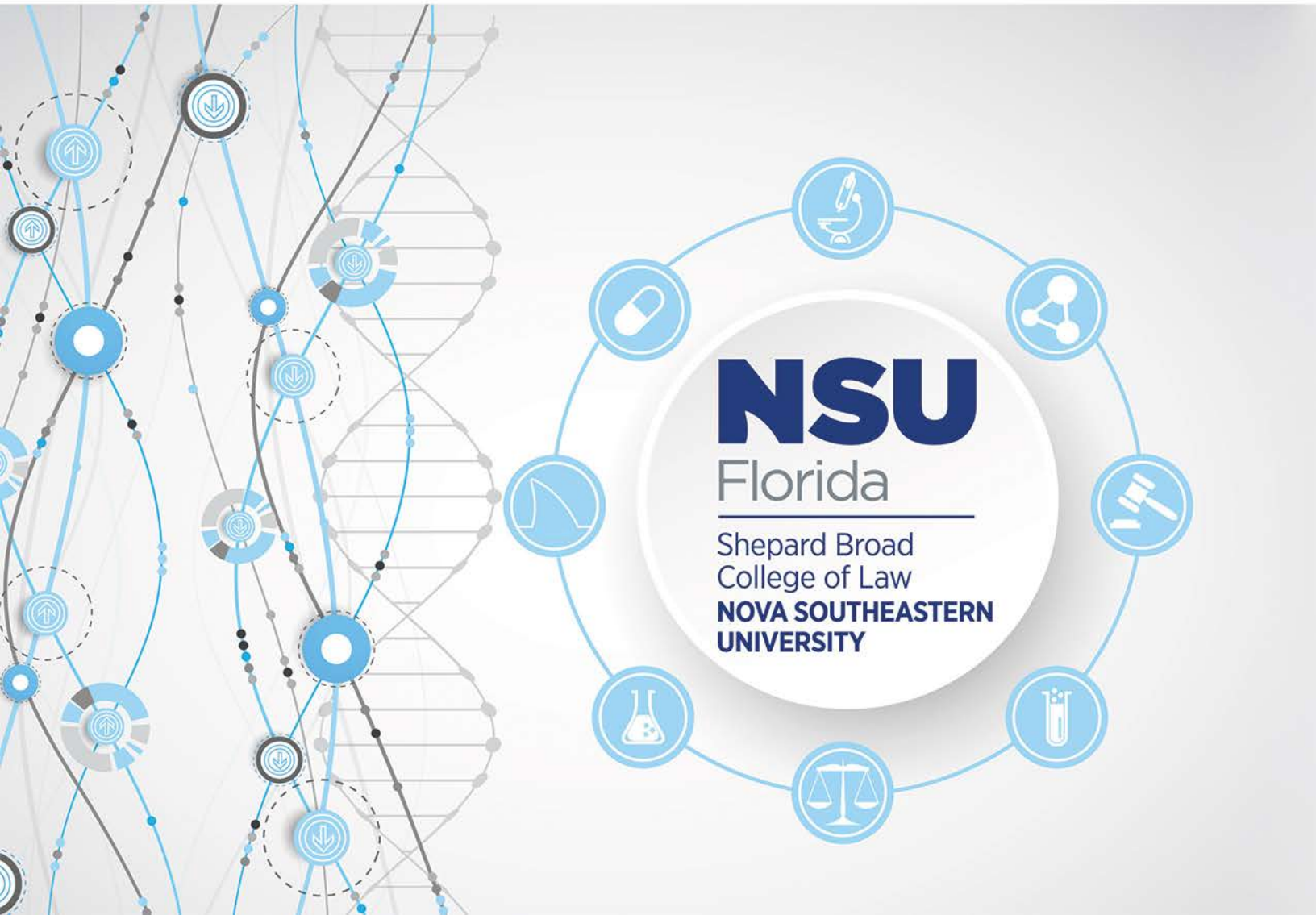
# FIRST DO NO HARM: A PATIENT-DRIVEN APPROACH TO NAVIGATING THE HEALTH LAW, INTELLECTUAL PROPERTY, AND TECHNOLOGY MAZE

**2019** NOVA LAW REVIEW SYMPOSIUM | **OCTOBER 11**



Shepard Broad College of Law
NOVA SOUTHEASTERN UNIVERSITY
NSU Florida

NOVA LAW REVIEW
NOVA SOUTHEASTERN UNIVERSITY

2019 Nova Law Review Symposium

# First Do No Harm: A Patient-Driven Approach to Navigating the Health Law, Intellectual Property, and Technology Maze

Friday, October 11, 2019 | Shepard Broad College of Law

Two of the fastest growing areas in the modern economy are health care and technology. In the race to provide innovations in health care and technology, however, the patient and caregiver are often left out of the conversation. Consequently, some technologies, intellectual property rules, health care options, and health policy decisions are replete with unintended consequences. This symposium considers social, ethical, and legal challenges posed by three developments in particular: creation and use of a medical information data commons, use of advanced technology to promote and maintain health, and human genome editing.

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| 8:00 – 8:45 am | **Continental Breakfast** | |
| 8:45 –9:00 am | **Welcome & Introductions** | **Danna Khawam,** Nova Law Review Editor-in-Chief<br>**Kathy Cerminara**, Professor of Law, NSU College of Law |

**PANEL1: What Would a Medical Data Information Commons Look Like, and How Would It Be Governed?**

The National Academies of Sciences has recommended development and use of a Medical Information Commons (or multiple such collections of data) to enhance medical progress and inform a learning health care system. In this panel, scholars will discuss how and why such efforts are proceeding and will examine the challenges presented by such development and use.

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| 9:00 – 10:30 am | **Moderator:** | **Marilyn Uzdavines,** NSU Law Professor |
| | **Speakers on Panel:** | **Marielle S. Gross, MD, MBE,** About Me, But Not for Me: The Ethical-Legal Gray Zone of Deidentified Health Data<br>**Melissa M. Goldstein, J.D.,** Redefining Sensitive Data<br>**Sharon Bassan, Ph.D.,** Active Users? The Roles of Data Subjects in Managing Their Data |
| 10:30 – 10:45 am | **Break** | |

**PANEL2: Patient Protection or Caveat Emptor? (Some) Risks Posed By High-Tech, Data-Driven Medicine**

Artificial intelligence, data collection apps, decision-support software, and other high-tech tools improve medical care in a variety of ways. Such innovation can enhance patient care, provide information at never-before-available levels of detail, and pose ethical challenges. These speakers will address a variety of medical-technological tools and consider their implications for the future of medical care.

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| 10:45 – 12:15 pm | **Moderator:** | **Robert Kain**, Shareholder, Kain Speilman PA |
| | **Speakers on Panel:** | **Yaniv Heled, J.S.D., LL.M., LL.B,** Competition in Biological Pharmaceutical Markets<br>**Bethany Corbin, J.D., LL.M.,** FemTech: Societal, Ethical, and Privacy Implications of Digitizing the Female Body |

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| | | **Jennifer Wagner, J.D., Ph.D.,** Precision Medicine and the FTC |
| 12:15 – 1:15 pm | **Lunch** | |

**PANEL3: Will Human Gene Editing Improve Health, Promote Eugenics, Or Both?**

In late 2018, Dr. He Jiankui stunned the world by announcing that he had performed human germline editing on twin baby girls in China. The case not only ignited a firestorm of debate over its particular facts, but it also prompted renewed attention to even non-germline genome editing, testing, or screening. Medical researchers have been virtually unanimous in saying that the new tool facilitating this editing should not be used on human germlines until more is known. This panel attempts to identify that "more," and consider regulatory solutions, in the context of both the He case and the type of genetic editing that proceeds every day.

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| 1:15 – 2:45 pm | **Moderator:** | **Kathy Cerminara**, Professor of Law, NSU College of Law |
| | **Speakers on Panel:** | **Myrisha Lewis, J.D.,** The Coming Age of Gene Editing: Medical Promise, Regulation, and the Revival of Decades of Debate<br>**Seema Mohapatra, J.D., MPH,** Regulating Human Germline Editing<br>**Samantha Zyontz, Ph.D.,** Running with (CRISPR) Scissors: Tool Adoption and Team Assembly<br>**Jonas Monast, J.D.,** Governing Extinction in the Era of Gene Editing |
| 2:45 – 3:30 pm | **Question & Answer Session** | **Danna Khawam,** Nova Law Review Editor-in-Chief<br>**Robert Scheppske,** Nova Law Review Goodwin Alumni Editor |
| 3:30 – 4:30 pm | **Closing Remarks and Reception** | |

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**The Florida Bar Certificate of Accreditation for Continuing Legal Education**

Reference No.: Pending
Title: Nova Law Review Symposium
Level: Intermediate

## Welcome from the Nova Law Review

On behalf of the Executive Board of the Nova Law Review, welcome to the 2019 Nova Law Review Symposium, First Do No Harm: A Patient-Driven Approach to Navigating the Health Law, Intellectual Property, and Technology Maze. This Symposium provides an opportunity for scholars to discuss the technological advances in the health care system along with the effects technology has on patients and caregivers. The three panels will comprise of presentations on medical data information, patient protection, and human gene editing.

Topics of discussion will include: Health data ownership; de-identified health data; defining sensitive data; role of data subjects; competition in pharmaceutical markets; implications of digitizing the female body; precision medicine; gene editing; and CRISPR (genome editing technology).

Attendees will have the unique opportunity to learn from distinguished attorneys and law professors from across the United States including representatives from Johns Hopkins Berman Institute of Bioethics, George Washington University, William & Mary Law School, Wake Forest University, Stanford Law School, among many others. Overall, the goal of this Symposium is to discuss the role of the patient in the health care industry and the unintended consequences of recent innovations to health care options.
We sincerely thank you for attending and hope you enjoy the presentations.

**Danna Khawam**,
Juris Doctor Candidate | 2020
Nova Law Review | Editor-in-Chief, Vol. 44
Nova Southeastern University | Shepard Broad College of Law

**#NLRSymposium2019**

**Danna Khawam,**
Nova Law Review
Editor-in-Chief, Vol. 44

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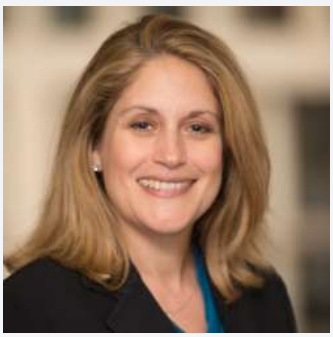
## PANEL 1: WHAT WOULD A MEDICAL DATA INFORMATION COMMONS LOOK LIKE, AND HOW WOULD IT BE GOVERNED?

### Marielle S. Gross, MD, MBE

Marielle S. Gross, MD, MBE is a graduate of Columbia University and the Jewish Theological Seminary where she studied moral and religious philosophy prior to completing a master's in Bioethics at New York University. She then received her MD from the University of Florida College of Medicine, completed her residency in Gynecology & Obstetrics at Johns Hopkins University, and is currently a Hecht-Levi Postdoctoral Fellow at the Johns Hopkins Berman Institute of Bioethics. Dr. Gross's research focuses on the role of innovative technologies in promoting the evidence-basis and equity for women's healthcare, and on dismantling "prejudice based medicine (PBM):" health policy and practices which are not evidence-based and which tend to exacerbate disparities. Her work currently covers applications of blockchain and privacy-preserving technology for the purposes of building and implementing an ethically responsible learning healthcare system and she is exploring development of new ethical, legal, social and technological guidelines for health data treatment in clinical and research contexts empowered by next-generation artificial intelligence. In addition to her research, she is a practicing OB/GYN physician, an IRB board member, and is developing simulation-based medical ethics curriculum for women's health trainees.



### Melissa M. Goldstein, J.D.

Melissa M. Goldstein, JD is an Associate Professor in the Department of Health Policy and Management at the Milken Institute School of Public Health at the George Washington University, where she teaches courses in bioethics (including genomics, privacy, reproductive ethics, end-of-life, and research ethics issues), health information technology policy, and public health law and conducts research on health information privacy and the legal and policy aspects of health information technology. Professor Goldstein's recent research and writings have focused on privacy and security issues in health information exchange and the use of big data, as well as the effects of health information technology on the physician-patient relationship and patient engagement. During the 2010-2011 academic year, Professor

Goldstein served as a senior advisor to the Chief Privacy Officer in the Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services. Professor Goldstein also served as the Assistant Director for Bioethics and Privacy in the White House Office of Science and Technology Policy during the final year of the Obama Administration.

## Sharon Bassan, Ph.D.

Sharon is a legal scholar with expertise in health law and policy, innovation and information technology law, and (bio)ethics. She is currently the Jaharis Faculty Fellow in Health Law and Intellectual Property at the DePaul University College of Law, after two years as a Postdoctoral Research Associate at the University Center for Human Values (UCHV), Princeton University. Her research addresses emerging technologies that lack a clear regulating authority or a cohesive regulatory framework, which raise ethical challenges and often, commercial interests. Sharon's recent and forthcoming work explores the regulation of reproductive practices and information technologies such as data mining, Big Data, and intelligent systems.

## PANEL 1 Moderator: Marilyn Uzdavines

Professor Marilyn Uzdavines is a 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.

## PANEL 2: PATIENT PROTECTION OR CAVEAT EMPTOR? (SOME) RISKS POSED BY HIGH-TECH, DATA-DRIVEN MEDICINE

### Yaniv Heled, J.S.D., LL.M., LL.B.

Yaniv Heled's research focuses on legal and ethical aspects of biomedical technologies. He has written on such topics as the regulation of biologics and biosimilars, stem cells, human reproductive tissue, DNA sequencing and testing, and more. His recent notable scholarship includes the article, "Follow-On Biologics Are Set Up to Fail," which explains why there is not going to be meaningful competition in biologics under current market and regulatory conditions. In another article, "Why Healthcare Companies Should (Be)come Benefit Corporations," Heled and co-authors, Liza Vertinsky and Cass Brewer, make the case for requiring companies involved in the provision of healthcare products and services to incorporate (or re-incorporate) as benefit corporations, a relatively new type of business entity which is required to consider not only corporate profits but also public health.

Heled is on the faculty of Georgia State University's Center for Law, Health & Society and is the Co-Director of the Georgia State University Center for Intellectual Property Law. He teaches the courses: Patent Law, Family Law, Law & Biotechnology, Policy & Ethics, and Different & Unusual Forms of Intellectual Property.

Prior to joining Georgia State Law, Heled practiced intellectual property law with Goodwin Procter LLP in New York.

Heled earned a J.S.D. from Columbia University School of Law. His doctoral dissertation focused on the regulation of novel biomedical technologies. In addition, Heled holds an LL.M. from Columbia, where he was a Harlan Fiske Stone Scholar, and an LL.B. and undergraduate Diploma in Biology, magna cum laude, from Tel Aviv University.

## Bethany Corbin, J.D., LL.M.

Bethany Corbin is the Director of the Master of Studies in Law program at Wake Forest University School of Law, and an enthusiastic professor on health care law and policy, privacy and emerging technologies, administrative law, and torts. She received her LL.M. in Health Law from Loyola University of Chicago and her J.D. from Wake Forest University School of Law. Bethany is a Certified Information Privacy Professional (CIPP/US), and is Certified in Healthcare Compliance and Healthcare Privacy Compliance. She currently focuses her scholarship on the intersection of health care and technology, with a particular emphasis on digital health, the Internet of Medical Things, and medical devices.

## Jennifer Wagner, J.D., Ph.D.

Dr. Jennifer K. Wagner is associate director of bioethics research and assistant professor in the Center for Translational Bioethics & Health Care Policy at Geisinger, and is a licensed practicing attorney in Pennsylvania. She earned her JD at the University of North Carolina in 2007 and PhD in anthropology at Pennsylvania State University in 2010 before completing post-doctoral research appointments at Duke University's Institute for Genome Sciences & Policy and the University of Pennsylvania's Center for the Integration of Genetic Healthcare Technologies. Prior to joining Geisinger, Dr. Wagner served in a U.S. Senator's office in Washington, DC, as a 2014-2015 AAAS Congressional Fellow and for several

years was a contributing editor for the Genomics Law Report. She is the 2019 chair of the ASHG Social Issues Committee and member of the AAPA Science Policy and Ethics Committees. Some of her research has been cited by the U.S. Supreme Court and funded by the National Human Genome Research Institute.

## PANEL 2 Moderator: Robert Kain

Robert Kain is a Shareholder of Kain Spielman and has practiced intellectual property law for more than three decades. He is Board Certified in Intellectual Property Law by the Florida Bar and was a founding member of the Intellectual Property Certification Committee appointed by the President of the Florida Bar. Robert has been honored as AV Rated with Martindale Hubble and with the Super Lawyers Award. Ultimately, he was appointed Chairman of that Committee. He is past Chairman of the Computer and Technology Law Committee of the Florida Bar. Robert also lead a three year effort by the Florida Bar Business Law Section to enact a new Florida law, the Computer Abuse and Data Recovery Act (CADRA), F.S. 668.801 which provides a civil remedy for businesses who suffer losses when their computer systems are hacked by unauthorized users. Robert was Chairman of the CADRA task force.

He has B.E. Degree in Electrical Engineering and Law Degree from Vanderbilt University. Robert drafted his first computer system patent in 1982 working as patent counsel for General Electric. Since that time, he has authored hundreds of computer program patents and has published more than three law review and journal articles on computer and Internet law. He secures patent and trademark rights, both domestically and internationally for his clients. Robert also litigates patent, trademark, copyright and Internet related disputes throughout the United States, in District courts and before the Patent Trial and Appeal Board. He is well versed in the highly technical fields of computer and Internet law.

He is a registered patent attorney with the U. S. Patent and Trademark Office and is admitted to the Bars of Florida, New York, the District of Columbia, numerous U.S. District Courts and many U.S. Circuit Court of Appeals. Robert taught patent law, as an adjunct professor of law, at Nova Southeastern University Law School, continues to lecture at various CLE seminars and has published over 10 law review and law related articles in the I.P. field.

## PANEL 3: WILL HUMAN GENE EDITING IMPROVE HEALTH, PROMOTE EUGENICS, OR BOTH?

### Myrisha Lewis, J.D.

Myrisha Lewis is an Assistant Professor at the William & Mary Law School. Professor Lewis earned a law degree from Columbia Law School and an A.B. in Government from Harvard College. During law school, she was a case law editor of the Columbia Journal of European Law. Prior to joining the William & Mary Faculty, she was an Assistant Professor at the Howard University School of Law and a Visiting Assistant Professor at the IIT Chicago-Kent College of Law. Professor Lewis' research considers how health law, family law, and criminal law respond to scientific innovations. Her work has been published in the Utah Law Review, Cardozo Law Review, Wisconsin Journal of Law, Gender and Society, Charleston Law Review, Nevada Law Journal, and William and Mary Journal of Women and the Law. In 2019, a forthcoming article will be published by the American Journal of Law and Medicine.

### Seema Mohapatra, J.D., MPH

Seema Mohapatra, JD, MPH is a tenured faculty member at the Indiana University Robert H. McKinney School of Law. She teaches Health Care Law, Torts, Genetics and the Law, Women's Health and the Law, and Bioethics. She earned her law degree from Northwestern University School of Law and her Master's in Public Health degree from Yale University in Chronic Disease Epidemiology. Prior to her career in academia, she practiced health care law at Sidley Austin in Chicago for several years. She is an expert in the areas of bioethics, assisted reproduction, public health law, torts, and health disparities. Her research interests include the intersection of biosciences and the law, assisted reproduction and surrogacy, health care disparities in the United States, and informed consent. Her work has been published in several journals, including the Wake Forest Law Review, Colorado Law Review, Brooklyn Law Review, and the Harvard Journal of Law & Policy, and she is an author and co-editor (with Lindsay Wiley) on a book entitled Feminist

Judgments: Rewritten Health Law Opinions, which is currently under contract with Cambridge University Press.

## Samantha Zyontz, Ph.D.

Dr. Zyontz is currently working with Mark Lemley and Lisa Larrimore Ouellette as a Research Fellow in Intellectual Property at Stanford Law School where her research interests include the effect of knowledge and tools on the direction of research ideas, intellectual property strategy, and the influence of institutions on the rate and direction of innovation. Her projects and publications have empirically analyzed a range of topics including the introduction of breakthrough innovations like the CRISPR DNA-editing system, patent damage awards, business method patents, clusters of related industries, cy pres awards in class action lawsuits, arbitration, and state consumer protection acts. She previously worked with Michael Porter and his team at the Institute for Strategy and Competitiveness at Harvard Business School on the federally sponsored U.S. Cluster Mapping Project. Dr. Zyontz has also managed a number of policy focused, large-scale empirical law and economics projects for the Searle Center on Law, Regulation, and Economic Growth at Northwestern University School of Law and the Law and Economics Center at George Mason University School of Law. Prior to her career in academia, she spent seven years working in intellectual property litigation and valuation consulting for PricewaterhouseCoopers, LLP and Navigant Consulting, Inc. Dr. Zyontz received her Ph.D. and S.M. in Technological Innovation, Entrepreneurship, and Strategic Management from the MIT Sloan School of Management, a M.S. in Managerial Economics and Strategy from the Kellogg School of Management at Northwestern University and graduated Phi Beta Kappa from the College of William & Mary in Virginia with a B.A. in economics and a minor in business marketing.

## Jonas Monast, J.D.

Jonas Monast is the C. Boyden Gray Distinguished Fellow at the University of North Carolina School of Law and serves as the director of the UNC Center on Climate, Energy, Environment & Economics (CE3). His scholarship focuses on climate change mitigation, governing the evolving electricity sector, and the intersection between natural resources and emerging technologies. Prior to joining the UNC faculty, he

directed the Climate and Energy Program at Duke University's Nicholas Institute for Environmental Policy Solutions.

## PANEL 3 Moderator: Kathy Cerminara

Professor Kathy Cerminara bridges the medical n 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.

# Dean Jon M. Garon

Jon M. Garon is Dean of Nova Southeastern University Shepard Broad College of Law. Dean Garon serves as chief academic officer for the law school, providing strategic leadership on programming, curriculum, enrollment management, marketing, and finance. He is a nationally recognized authority on technology law and intellectual property, particularly copyright law, entertainment and information privacy. A Minnesota native, he received his bachelor's degree from the University of Minnesota in 1985 and his juris doctor degree from Columbia University School of Law in 1988.

Prior to joining Nova Southeastern University in 2014, Garon was the inaugural director of the Northern Kentucky University Salmon P. Chase College of Law, Law + Informatics Institute from 2011-2014. The Law + Informatics Institute serves to integrate the specialized programming on technology and information systems as they apply across legal disciplines. A tenured member of the law faculty, Garon taught Information Privacy Law, Cyberspace Law, Copyright Law, Entertainment Law, and related courses.

Garon served as dean and professor of law at Hamline University School of Law in St. Paul, Minnesota. He was professor of law from 2003 to 2011, dean of the Law School from 2003 to 2008 and Interim Dean of the Graduate School of Management from 2005 to 2006. Before Hamline, Garon taught Entertainment Law and Copyright at Franklin Pierce Law Center in Concord, New Hampshire and Western State University College of Law in Orange County, California.

Among his numerous accomplishments, Garon has held key leadership positions as past chair of both the American Bar Association's Law School Administration Committee and the Association of American Law Schools Section on Part-Time Legal Education. His teaching and scholarship often focus on business innovation and structural change to media, education and content-based industries. He is the author of three books and numerous book chapters and articles, including The Independent Filmmaker's Law & Business Guide to Financing, Shooting, and Distributing Independent and Digital Films (A Cappella Books, 2d Ed. 2009); Own It – The Law & Business Guide to Launching a New Business Through Innovation, Exclusivity and Relevance (Carolina Academic Press 2007); and Entertainment Law & Practice (2d Ed. 2014 Carolina Academic Press). Additionally, he has presented at more than 60 forums across the U.S.

## Danna Khawam, Nova Law Review Editor-in-Chief

Danna Khawam is currently a Juris Doctor Candidate for May 2020 at Nova Southeastern University, Shepard Broad College of Law. Danna is the Editor-in-Chief of Nova Law Review, Volume 44. Her article, titled Is the End to the Opioid Epidemic Near? Florida and Other States Attempt to Address the Crisis by Passing New Limits on Opioid Prescriptions, was published in the 2018 Florida Book (Vol. 43, Issue 1) of the Nova Law Review. She is also a member of President's 64, Moot Court Society, and the Honors Program. Danna worked as a Summer Associate at Nelson Mullins Broad and Cassel this past summer. Last summer, she interned at Environmental and Consumer Protection Division in Broward County, Florida.

During her first year of law school, Danna won the Martin Luther King Writing Competition and was the runner-up in the 1L Feinrider Moot Court Competition. As a 2L, Danna competed in the Health Law Competition and ended as an octofinalist. In her last year of law school, Danna will compete in the ABA Moot Court Competition.

Danna holds a degree in Political Science from Fordham University. At Fordham, Danna also minored in Psychology and Arabic. She was the Co-President of the Fordham Club. Danna interned at multiple law firms, including Callagy Law and Davidson & Grannum, while she was an undergraduate student.

## Robert Scheppske, Goodwin Alumni Editor

Bobby Scheppske first got involved in Nova Law Review in Fall 2018 as a junior associate. This year, he will help run the Law Review Symposium as the Goodwin Alumni Editor. In addition to his involvement in law review, Bobby is the incoming Chief Justice for Moot Court and participates in NTA and Presidents 64.