

2022

2022

Southern Methodist University, Dedman School of Law, Tsai Center for Law, Science and Innovation

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Considering Options

Professors gather to discuss patent system's architecture

JUDGING by the attendance and lively discussion at the Tsai Center's Symposium on Emerging Intellectual Property Issues, there is much interest in the institutional makeup of our nation's patent system and the role of District Courts, the Federal Circuit, and the Patent Trial and Appeal Board. The symposium, entitled "Patent Law and Institutional Choice," included three sessions, featured nine speakers, and attracted about 90 participants. Each panel explored a different aspect of the institutional structure of the U.S. patent system, the roles of its institutions, and how the patent system may be improved to further the innovation economy.

Clustering of patent cases

The symposium's first panel discussed the clustering of patent cases in various federal district courts, including the Western District of Texas.

Panelists for this session included:

- **Jonas Anderson**, American University Washington College of Law
- **Megan M. LaBelle**, Catholic University of America Columbus School of Law
- **Greg Reilly**, Illinois Tech Chicago-Kent College of Law

Professor Anderson outlined three options for addressing forum shopping and forum selling: randomization of assignment of cases,

SEE CONSIDERING OPTIONS ON PAGE 4



Medicine + AI

Medical, technical, and legal experts came together at the SMU Science and Technology Law Review's annual symposium to address how their respective professions can stay ahead of the burgeoning, brave new world of medical artificial intelligence. Tsai Center Co-Director and SMU Dedman School of Law Professor **Nathan Cortez** welcomed both in-person and online participants. "It is our responsibility as legal and medical professionals to shape how laws and ethical frameworks adapt to new technologies. We are not speculating on the future: The future is now," he said.

SEE MEDICINE + AI ON PAGE 7

Tsai Team

CO-DIRECTORS AND EXECUTIVE BOARD

Lackland H. Bloom, Jr., Larry and Jane Harlan Senior Research Fellow and Professor of Law

Nathan Cortez, Co-Director of Tsai Center for Law, Science and Innovation and Adelfa Botello Callejo Endowed Professor of Law in Leadership and Latino Studies

Chris Jenks, Director of the Criminal Clinic and Professor of Law

Orly Mazur, Associate Professor of Law

Jason P. Nance, Judge James Noel Dean and Professor of Law, *ex officio*

Carla L. Reyes, Assistant Professor of Law

Meghan J. Ryan, Co-Director of Tsai Center for Law, Science and Innovation, Altshuler Distinguished Teaching Professor, and Professor of Law

David O. Taylor, Co-Director of the Tsai Center for Law, Science and Innovation, Robert G. Storey Distinguished Faculty Fellow, and Professor of Law

STAFF

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Rachel Gillespie
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Serene Zidan
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TSAI CENTER

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From the Co-Directors

WE INVITE YOU to read the pages of this newsletter to learn more about the activities of the Tsai Center in our most recent academic year. We enjoyed hosting two symposia, one focusing on artificial intelligence and healthcare and another focusing on the institutions of the U.S. patent system. Our Tsai Scholars organized several Tsai Talks, addressing diverse issues including pharmaceutical innovation; name, image, and likeness deals for student athletes; race and intellectual property; non-fungible tokens; and venture transactions. The Center sponsored important work of SMU Dedman School of Law faculty at the intersection of law, science, and innovation. In the pages of this newsletter we also continue our tradition of recognizing outstanding SMU Law graduates who have made an impact in the world of law, science, and innovation. This year we highlight Michael Boone '67 and salute him for his decades of service to SMU, SMU Dedman School of Law, and the greater legal profession. We hope to see you at our next event!

Nathan Cortez

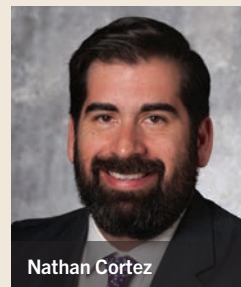
CO-DIRECTOR OF THE TSAI CENTER FOR LAW, SCIENCE AND INNOVATION AND PROFESSOR OF LAW

Meghan J. Ryan

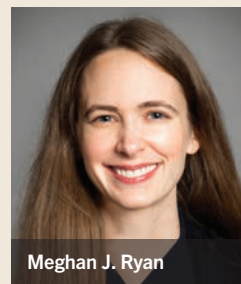
CO-DIRECTOR OF THE TSAI CENTER FOR LAW, SCIENCE AND INNOVATION AND PROFESSOR OF LAW

David O. Taylor

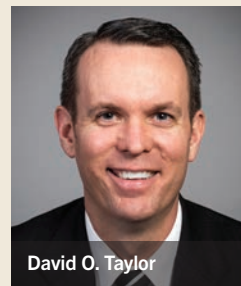
CO-DIRECTOR OF THE TSAI CENTER FOR LAW, SCIENCE AND INNOVATION AND PROFESSOR OF LAW



Nathan Cortez



Meghan J. Ryan



David O. Taylor

CENTER UPDATE

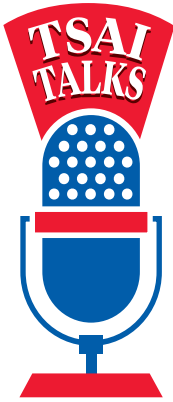
Tsai Center Adds New Co-directors

● The Tsai Center is pleased to announce that SMU Provost **Elizabeth Loba** and SMU Dedman School of Law Dean *ad interim* **Thomas Mayo** recently appointed two additional co-directors to lead the Tsai Center. SMU Professors **Nathan Cortez** and **Meghan J. Ryan** will join the Tsai Center's founding co-director, **Professor David O. Taylor**.

Professor Cortez serves as a Gerald J. Ford Research Fellow and the inaugural Adelfa Botello Callejo Endowed Professor of Law in Leadership and Latino Studies. He teaches and writes in the areas of health law, administrative law, and FDA law, and his research focuses on emerging markets in health care and biotechnology. Professor Cortez's expertise will aid the Center as it seeks to expand its activities in the area of health care innovation and the ethical, legal, and social implications of new health technologies.

Professor Ryan serves as an Altshuler Distinguished Teaching Professor and Professor of Law. She teaches and writes at the intersection of criminal law and procedure, torts, and law and science. Her research focuses on the impact of evolving science, technology, and cultural values on criminal convictions and punishment, as well as on civil remedies. Her on-going work will help the Center collaborate with engineering, science, and philosophy departments at SMU and other universities.

"Professors Cortez and Ryan each bring valuable expertise and experience to the Tsai Center," said Professor Mayo. "We are excited to have such a distinguished and experienced team leading the Tsai Center."



SEPTEMBER 9, 2021

White Coats and Black Robes: Pharmaceutical Innovation and the Law

Frank Grassler, a Member of Martin Fulton, PLLC, participated in the semester's first Tsai Talk. He shared insights about pharmaceutical innovation and the law. He also discussed his career, including his transition from serving as a pharmacist to serving as a patent attorney for GlaxoSmithKline.

OCTOBER 6, 2021

Let them Play (and get Paid): Name, Image and Likeness Deals and NCAA Compliance

Damilola Sule, SMU Director of Compliance, and Rob Heuer, SMU Assistant Athletic Director for Compliance, discussed effects of the recent Supreme Court decision in *NCAA v. Alston* on name, image, and likeness deals for student athletes, the innovative ways that student athletes can pursue these deals, and careers in NCAA compliance.

MARCH 10, 2022

Race and Intellectual Property: What? Why?

Michael D. Pegues, Shareholder and Chair of the Intellectual Property Litigation Practice at Polsinelli and Adjunct Professor at SMU Dedman School of Law, examined how intellectual property law, principles, and policies have used race to perpetuate divisions between and among groups of people.



MARCH 22, 2022

What's so NiFTy about NFTs?

Rocio Palomo, Counsel with Perkins Coie, discussed the basics of non-fungible tokens (NFTs), the current NFT marketplace, and how she advises clients on what NFTs mean for their businesses.

APRIL 7, 2022

Successful Innovation: Startups and Venture

Kevin Vela, Managing Partner with Vela Wood, explored how startups and venture transactions have evolved in contemporary society and their continued intersection with technology.



Incoming Tsai Scholars Rachel Gillespie, Ian Johnson, Val Morrow, and Serene Zidan at the May 2022 Tsai Scholars End of Year Celebration

THE TSAI SCHOLARS PROGRAM

Experience, Collaboration, and Connection

Each year the Tsai Center names a handful of the law school's most successful students as Tsai Scholars. The Tsai Scholars program is a cornerstone endeavor of the student-focused efforts of the Tsai Center. The program gives these students valuable experiences working closely with Tsai Center Co-Directors to provide research assistance and event support for the Center's programs. Along the way, these students develop important personal and professional connections with attorneys, professors, and each other.

Tsai Scholars plan and execute Tsai Talks—presentations and discussions by working attorneys that bridge the real world of science, innovation, and law with the classroom. Tsai Scholar **Marisa Thompson '22** recalled a Tsai Talk focused on influencer marketing and social media. "We brought in a practitioner to teach [students] about the regulatory landscape of that space and careers at the intersection of social media and law," said Thompson. "These types of topics and events were unique to the Tsai Center, and I loved being a part of them."

Tsai Scholar **Dylan Freeman '22** reflected on his support of faculty research with his work on Fed Circuit Blog, which documents activities of the federal appellate court that holds exclusive jurisdiction over appeals in patent cases. "I saw more court briefs and heard more legal arguments over current law working for the Tsai Center than I saw in any classroom," said Freeman. Thompson agreed. "Working as a Tsai Scholar helped me gain a familiarity with the work of the Federal Circuit that very few of my peers had," she explained.

Elizabeth Chung Hatrup '20 also served as a Tsai Scholar. She entered law school uncertain how she would combine her interest in intellectual property and technology and her five years of experience in business analytics. Asked how working as a Tsai Scholar benefitted her professional development and career, Hatrup explained, "It helped me to understand that I could merge my legal background and my business background." She noted how "the program opened [her] eyes to all of the opportunities available to law students in the Dallas community" and gave her the opportunity to interact with both in-house counsel and attorneys at major law firms.

Both Thompson and Freeman were able to use their experiences as Tsai Scholars to secure post-graduate federal judicial clerkships. "I walked out with a deep understanding of the settled law and current hot issues" in the field of patent law, Freeman said. "During interviews," Thompson added, "I could speak with clarity to different areas of the current practice of patent law because of activity I saw on the Fed Circuit Blog."

Beyond preparing these students for their careers, the Tsai Scholars program helped these students develop personal and professional connections. "The best part of being a Tsai Scholar was the one-on-one facetime with the professors," said Freeman. Hatrup appreciated how much the program pushed her to network outside of her niche group, stating that "the greatest thing about being a Tsai Scholar is the people

SEE TSAI SCHOLARS ON PAGE 4

CoverStory

Considering Options

CONTINUED FROM THE COVER

change in the venue statute, and having patent-focused judges in each district.

Professor LaBelle added her own suggestions. “Local patent trials need some conformity in rules and procedures,” she stated. “Presently, procedural law is not the same from district to district.”

Professor Reilly, in turn, called for judicial restraint. “There is a need for more modesty,” he said.

This panel also debated whether the U.S. Court of Appeals for the Federal Circuit should police forum shopping and forum selling, or whether Congress should address the clustering of patent cases.

The Role of the PTAB and USPTO Director

The second session considered the makeup, function, and oversight of the United States Patent and Trademark Office’s Patent Trial and Appeal Board. Created by Congress in 2011, the PTAB is made of Administrative Patent Judges appointed by the Secretary of Commerce to hear disputes over the validity of patent claims.

Panelists included:

- **Tejas N. Narechania**, University of California, Berkeley,
- **Jason Rantanen**, University of Iowa College of Law
- **A. Cristal Sheppard**, Former Regional Director of the Elijah J. McCoy Midwest Regional United States Patent and Trademark Office

The session began with Professor Rantanen’s review of the Supreme Court’s recent ruling that the manner of APJ appointments was incompatible with the Constitution’s Appointments Clause. To



“The Federal Circuit Court was a 39-year experiment in specialization.”

— PROF. PAUL GUGLIUZZA

remedy the infirmity, the Court ruled that the USPTO’s Director, who is nominated by the President and confirmed by the Senate, has final review of PTAB decisions. Professor Rantanen highlighted that some members of Congress have called for a more radical restructuring of authority.

Professor Narechania discussed that “political accountability matters,” noting that the USPTO Director wields a great deal of power. “There are different philosophical views on the patent process, such that settling disputes should be a matter of the political process.”

Professor Sheppard focused attention on the result of the current administrative scheme. “The goal of the PTAB,” she explained, “was to reduce the administrative burden on the USPTO, to result in cost savings and greater efficiency.” But, she lamented, “these have not happened.”

The panel concluded with a discussion of options for restructuring the review process.

The Federal Circuit and SCOTUS

The third session considered the interaction between the Federal Circuit and the Supreme Court. Panelists included:

- **Laura Pedraza-Fariña**, Northwestern University Pritzker School of Law
- **Paul Gugliuzza**, Temple University Beasley School of Law
- **David O. Taylor**, SMU Dedman School of Law

Professor Taylor provided historical background on calls for the creation of a patent-focused appellate court. Over time, he explained, justifications changed from reducing the time for decisions to eliminating circuit splits regarding validity of patents to resolving circuit splits regarding patent law. He noted how the Federal Circuit was created in 1982 to remedy the last problem. But, he continued, given the Supreme Court’s recent interest in deciding patent cases, there appears to be need for a different justification for the Federal Circuit.

Professor Gugliuzza questioned whether the Federal Circuit should be abolished. As he put it, “The Federal Circuit Court was a 39-year experiment in specialization.” At some point, he said, the experimentation should be called complete and a conclusion should be reached. “Neither the patent system nor society is better off since the creation of the Federal Circuit Court,” he said.

Professor Pedraza-Fariña, in turn, observed two benefits of the Federal Circuit—uniformity and expertise. “Uniformity can be a product of clear rules that prevent bias,” she noted. But expertise, she believes, would be most helpful at the fact-finding stage in district courts or at the USPTO, not at the Federal Circuit. And while centralization or concentration can lead to expertise from exposure and continued practice, she cautioned that there is a risk of excessive deference to judges with expertise.

Tsai Scholars

CONTINUED FROM PAGE 3

you meet.” Tsai Center Director of Programs and Operations Natalie Thompson Greco '05 shared that “it’s a joy to work with these bright and energetic students. I love to see the progression from the fall semester’s first Tsai Scholars meeting to the year-end Tsai Scholars networking event. With their shared interests, teamwork, and time together, Tsai Scholars often grow from classmates to friends.” Thompson similarly reflected on the connections she made as a Tsai Scholar. “The Tsai Scholars program helps create a great community of law students and professionals, and I am proud to call my fellow Tsai Scholars my friends.”

Faculty Updates



● **Lackland H. Bloom, Jr.** – Larry and Jane Harlan Senior Research Fellow and Professor of Law: Prof. Bloom is writing a book entitled *Defiance*, which will focus on mass defiance of law in American history.



● **Nathan Cortez** – Co-Director of the Tsai Center for Law, Science and Innovation and Adelfa Botello Callejo Endowed Professor of Law in Leadership and Latino

Studies: Prof. Cortez was appointed as Co-Director of the Tsai Center for Law, Science and Innovation. He chaired this year's *SMU Science and Technology Law Review Symposium*, "Emerging Legal and Ethical Frameworks for A.I. in Medicine." He will publish "Licensing and Quality" in the *New England Journal of Medicine*, "The Disembodied First Amendment" in *Washington University Law Review*, and "Hortatory Mandates" in *George Washington Law Review*. His co-authored book, *Food and Drug Law: Cases and Materials*, is forthcoming.



● **Chris Jenks** – Director of the Criminal Clinic and Professor of Law: Prof. Jenks published "Loophole Allows Safe Haven for War Crimes Violators on U.S. Soil" in *Inside Sources*

and "Comprehensive Justice and Accountability in Ukraine" as part of the Articles of War, Ukraine Symposium organized by the Lieber Institute at West Point. He served on a panel entitled "Settlers in Syria: Turkish Population Transfers & International Law" at George Mason Law School Center for the Middle East. He presented "Autonomous Weapons Impact on International Governance" to the Global Governance of Emerging Technologies class at Arizona State; "Autonomous Weapons Impact on International Governance" at the Geneva Academy Military Briefing Series; and "Law of Armed Conflict" at the SMU Law Virtual Flash Class: Ukraine Russia War and Law. Prof. Jenks was quoted in a Politico article, "Why Prosecuting Russian War Crimes in Ukraine Could be Complicated."



● **Tom Mayo** – Dean *ad interim*, Senior Associate Dean for Academic Affairs, Altshuler Distinguished Teaching Professor, and Professor of Law: Prof. Mayo served as Dean *ad interim* of SMU Dedman School of Law in the summer of 2022. He was quoted this spring on National Public Radio and Kaiser Health News commenting on the effect of Texas abortion laws on care for miscarriages.



● **Orly Mazur** – Associate Professor of Law: Prof. Mazur published two new co-authored articles proposing tax reforms to enable states to tax digital activities: "Digital Taxation and the State Income Tax" and "Digital Tax Reform and the State Income Tax: Practical Considerations," both appearing in *Tax Notes State*. She has also done significant work related to blockchain in the tax space. Her most recent piece, "Can Blockchain Revolutionize Tax Administration?" will be published in *Penn State Law Review*.



● **Carla Reyes** – Assistant Professor of Law: Prof. Reyes was appointed as Chair of the Texas Work Group on Blockchain Matters. She was appointed with Prof. Andrea Tosato to serve as Associate Research Director for the Permanent Editorial Board for the Uniform Commercial Code. She published "Autonomous Corporate Personhood" in the *Washington Law Review* and "Creating Cryptolaw for the Uniform Commercial Code" in the *Washington & Lee Law Review*. Her article, "Emerging Technology's Language Wars: AI & Criminal Justice" will be published in *Penn Law's Journal of Law & Innovation*. She received a research scholarship from UNIDROIT to expand her "Language Wars" studies to capture international legal harmonization efforts and conducted this research onsite at UNIDROIT in July.



● **Meghan Ryan** – Co-Director of the Tsai Center for Law, Science, and Innovation, Altshuler Distinguished Teaching Professor, and Professor of Law:

Prof. Ryan was appointed as Co-Director of the Tsai Center for Law, Science and Innovation. Her article "Criminal Justice Secrets" was published in *American Criminal Law Review* and "Understanding Criminal Justice Innovations" will be published in the *Journal of Law & Innovation*. Her book chapters, "Compensation for Wrongful Conviction and Incarceration in the United States" and "A Catholic Perspective on Prison Conditions and Human Dignity," are also forthcoming.



● **David O. Taylor** – Co-Director of the Tsai Center for Law, Science and Innovation, Robert G. Storey Distinguished Faculty Fellow, and Professor of Law: Prof.

Taylor published "Immoral Patents," "On Patents and Appropriations—And Tragedies," and "Justice Breyer and Patent Eligibility" in the *Mississippi Law Journal*, *Washington and Lee Law Review*, and *University of Illinois Chicago Review of Intellectual Property Law*, respectively. He spoke at events held by the Washington and Lee University School of Law, University of Houston Law Center, Indiana University Robert H. McKinney School of Law, Texas Regional United States Patent and Trademark Office, American Association of Patent Judges, and United States Intellectual Property Alliance. He continues to serve as Editor of *Fed Circuit Blog*.



● **Jenia Turner** – Amy Abboud Ware Centennial Professor in Criminal Law and Gerald J. Ford Research Fellow: Prof. Turner published "Virtual Guilty Pleas"

in Penn Law's *Journal of Constitutional Law*. Her article "Transparency in Plea Bargaining," was cited by the Supreme Court earlier this year in *United States v. Taylor*. She presented "Defense Use of Digital Discovery in Criminal Cases" at Duke's Empirical Criminal Law Roundtable; "A Comparative Perspective on Plea Bargaining and the Trial Penalty" at the National Association of Criminal Defense Lawyers Presidential Summit; "Remote Criminal Justice" at the National Criminal Justice Association's Topical Policy Session and the Virtual Comparative Criminal Law Seminar; and "Virtual Guilty Pleas" at the University of Warwick Law School. She joined the new North Texas Federal Criminal Law American Inn of Court.

Alumni Spotlight

Michael Boone

Class of 1967

“I don’t really work with intellectual property and patent cases, but that’s a huge area for Haynes and Boone.”

This is characteristic modesty from **Michael M. Boone**, SMU Dedman School of Law Class of 1967.

After graduating from law school, Boone co-founded the Dallas-based international law firm of Haynes and Boone, LLP. Now with 18 offices in cities across the country and all over the world, the firm practices in practically every area of the law. But it has earned particular success in the area of intellectual property. Chambers USA, for example, recently recognized the firm as “particularly esteemed” for its practice before the U.S. Patent and Trademark Office. Intellectual Asset Management likewise designated Haynes and Boone as a “recommended firm” for patent law.

Building an IP firm, starting with Corporate Law

But it’s true: Boone does not call himself an intellectual property attorney.

Boone recalls when he and Richard Haynes started their two-person firm: “I started in tax, and branched out into mergers and acquisitions, and to banking and lending. I knew 100 percent that I didn’t want to do litigation. On the other hand, I did enjoy and have some talent for negotiation, understanding complex business issues, and taxation. We always hoped to build out a full-service firm.”

They succeeded, building their firm organically from two lawyers to now more than 600. “You couldn’t do that now,” says Boone. “These days you could only grow that large through mergers and acquisitions.” Indeed, Boone has seen a metamorphosis of the business of law in the United States. “I’ve been on the ground floor of the expansion of the law profession,” says Boone. “It was exciting for a boy from Texas.”

Building Schools, starting with Highland Park

Yes, it all started in Texas. Highland Park to be exact. Boone attended Hyer Elementary



“I’ve been on the ground floor of the expansion of the law profession. It was exciting for a boy from Texas.”

— MICHAEL M. BOONE

School, then H.P. Junior High and H.P. High School. He went on to SMU, where he earned a B.B.A. in 1964 and a J.D. in 1967.

It wasn’t long after his graduation from law school before Boone not only formed his own law firm, but also started giving back to the community, both to the Highland Park Independent School District and to SMU. As for HPIISD, Boone served on its Board of Trustees for many years, including as its President. As for SMU, Boone first taught corporate securities as an adjunct professor in the law school. Boone later served on the law school’s Executive Committee and, in 1996, was elected to SMU’s Board of Trustees.

Boone is bullish about the future of SMU and the Dedman School of Law. “SMU has always had a major strength in corporate and international law,” he explains. In fact, “SMU has had numerous very high-profile individuals in business, industry, finance, and government all around the world.” And Boone doesn’t see that changing.

“Dallas is a major hub for international business,” he highlights. “There will be more demands on SMU, more opportunities for SMU to serve these big corporations, so much more demand for legal education,” he predicts. “The more Dallas grows, the more SMU grows with it.” And, he exhorts, “A great city must have a great law school.”

Currently

These days, Boone is no longer building his law firm. “I used to work frequently until three or four in the morning—

whatever it took to serve the client. Now I have the luxury of having someone else do the heavy lifting,” he explains.

He and his wife, Marla, have two adult children, Maryjane Bonfield and Michael Boone, and five grandchildren. Maryjane earned her law degree from SMU and was elected recently to serve on the Board of Trustees for HPIISD. Michael works in private equity. The entire family still lives in Highland Park, near HPIISD’s new Michael M. Boone Elementary School.

Yes, HPIISD recently built and named an elementary school in honor of Boone. “It’s been kind of a weird, out-of-body experience,” says Boone. He marvels that kids have come up to him and thanked him for the school. “But I have to tell them ‘I didn’t build it.’”

He may not have built the elementary school bearing his name, but he does deserve credit for helping to build HPIISD, SMU Dedman School of Law, and Southern Methodist University into the school district, law school, and university that they are today. And he certainly may take credit for building a major international law firm known for its significant success in intellectual property law.

Of course, Boone’s characteristic modesty likely won’t allow him to claim too much of this credit.

Boone’s many awards and honors include Distinguished Alumnus of SMU Dedman School of Law (1990); Distinguished Alumnus of SMU (1996); and Distinguished Alumnus of Highland Park High School (1998).

CoverStory

Medicine + AI

CONTINUED FROM THE COVER

Panel I: Designing and Developing Medical AI

- Vishal Ahuja, SMU Cox School of Business
- Dominique Shelton Leipzig, Perkins Coie
- Rosina Samadani, Oculogica
- Uzma Samadani, Oculogica
- Samantha Ettari, Perkins Coie (Moderator)

Ms. Ettari asked the first set of panelists: “What barriers do developers face with AI and machine learning programs? And what should lawyers and policy makers know about the development process?”

Dr. Uzma Samadani explained that scientific discovery has traditionally been hypothesis-driven, but our understanding of diseases has become more complex. Dr. Rosina Samadani provided a real-life example from her work: traumatic brain injury. To date, she explained, diagnosis has been subjective, dependent on the patient’s input, such as assessment of fatigue or mental foginess. But now Oculogica’s EyeBOX tracks how cranial nerves are functioning and how they impact involuntary eye movement. This information, she highlighted, removes the volitional aspect of a patient’s reporting.

Professor Ahuja noted the recent steady and steep increase in investment in digital healthcare, which has doubled in the last year, both in number of deals and dollar amount of investment. AI and machine learning, he continued, are allowing for leaps forward in disease screening, pharmacovigilance, clinical trial design, intelligent case coordination, remote patient monitoring, and more.

Ms. Leipzig addressed legal concerns with digital medicine. Persistent challenges, she explained, include patient privacy and health inequity. “Presently there are no federal privacy laws, although some states and 150 other countries have laws that protect data privacy—that is, laws that address what is disclosed and what can be done with the data,” she said. “Business is leap-frogging over regulation.”

The panelists concurred that overarching challenges in medical AI and modeling are health equity and algorithmic fairness. The group discussed how “privacy by design” addresses how data is collected, where it’s stored, how it’s used, and how it’s secured—which requires intentionality and top-level corporate commitment.



Panel II: Implementation of AI

- Teodor Grantcharov, University of Toronto
- Dean Harvey, Perkins Coie
- Steve Miff, Parkland Center for Clinical Innovation
- Herbert Zeh, UT Southwestern Medical Center
- Jill Louis, Perkins Coie (Moderator)

The second panel allowed medical professionals to bring their experiences to the discussion. Dr. Miff, for example, reported that Parkland Health and Hospital System has deployed more than a dozen AI models. “We’ve had challenges and successes, as well as a few cuts and bruises along the way,” he said.

As a surgeon, Dr. Zeh began using robotic surgery that increased his dexterity and provided 3D visualization. He described how most AI models focus on decision-making tools, dexterity, and over-the-shoulder technology to supervise and evaluate practitioners. But AI can also be used for training and credentialing surgeons, and it can lead to safer surgery.

Dr. Grantcharov stressed that there is still much that is unclear. “AI is not the end goal; rather, the goal is to continuously improve and to provide super-safe care of patients,” he said. “All our tools and algorithms must be safe, transparent, and explainable.”

Mr. Harvey concluded with advice to law practitioners based on the panel’s discussion: “It’s our duty to understand technology and apply the law within the existing legal and regulatory framework.”

Keynote Address: FDA Regulation of AI and Machine Learning

- Bakul Patel, Food and Drug Administration

Keynote speaker Bakul Patel brought the perspective of the Federal Drug Administration and its mission of assessing the capabilities of digital healthcare companies. Patel explained how the FDA is addressing the challenge of AI by setting reporting standards with its digital health accountability plan and digital health pre-certification process. But, he stressed, regulatory agencies, including the FDA, must be afforded the

ability to experiment with policies and processes. Fortunately, he explained, there has been international collaboration among regulatory agencies regarding standard-setting. The FDA and two other federal agencies, moreover, have codified ten principles of best practices to guide machine learning development.

Reflecting on a point from the earlier panel discussions, Patel noted there is a profound concern about equity in digital healthcare. As AI models are used and modified, he highlighted how important it is to use racially diverse training data. Developers should actively seek out data that represents real-world diversity, including geographic, socio-economic, and racial diversity.

Panel III: Shaping Medical AI

- Dean I. Glenn Cohen, Harvard Law School
- Colleen Flood, University of Ottawa
- Zubin Khambatta, Perkins Coie
- Nicholson Price, University of Michigan
- Nathan Cortez, SMU Dedman School of Law (Moderator)

“Oversight is needed; a lot can go wrong. We first look to the FDA for regulation,” stated Professor Price. AI needs its own validation, integration, and fine-tuning on a case-by-case, rather than nationwide, basis, he explained. Unfortunately, clinical informatics require massive effort and resources. Price suggested a possible solution: outsourcing to reduce the cost of in-house evaluation. By increasing the volume and shareability, Price explained, evaluation can become more accessible.

Professor Cohen raised the issue of informed consent for use of AI. If doctors make a recommendation to a patient based on AI, he asked, must they inform the patient? It is critical, he described, that whenever AI is used, its algorithms should be explainable and its results interpretable.

Participants in the symposium contributed to a heightened understanding of the potential of AI to improve healthcare and raised awareness of competing concerns of privacy, equity of access, and algorithmic fairness. As AI solutions to medical challenges proliferate, indeed the future truly is now.

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TsaiEvents

COMING IN 2023

February 24, 2023

19th Symposium on Emerging Intellectual Property Issues

LOCATION

SMU Dedman School of Law
Hillcrest Classroom
6550 Hillcrest Avenue, Dallas TX

KEYNOTE ADDRESS

Karcher Auditorium
3315 Daniel Avenue, Dallas TX

5 hours
Texas MCLE
credit pending

REGISTRATION OPENS DECEMBER 1, 2022 For more information: Visit smu.edu/law/tsaicenter