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PROCEEDINGS OF THE 2020 LEE E. TEITELBAUM UTAH LAW REVIEW SYMPOSIUM

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In the autumn of 2020, the *Utah Law Review*, in cooperation with the S.J. Quinney College of Law Center for Law and Biomedical Sciences, convened a two-day virtual symposium exploring "The Law and Ethics of Medical Research." On November 13th, leading scholars from across the country joined us for a panel discussion titled "Sharing Medical Research Data: Privacy and Confidentiality." On November 20th, a second set of distinguished scholars and practitioners gathered virtually for three more panel discussions: "Clinical Trials—Legal and Ethical Issues in the Age of COVID-19," "Intellectual Property and Medical Research," and "Medical Research as a Public Health Initiative."

The pages that follow present summaries of those conversations prepared by S.J. Quinney College of Law students. Full video recordings of the panel discussions are posted on the S.J. Quinney College of Law YouTube channel located at https://perma.cc/LKF2-CKQ5.

SHARING MEDICAL RESEARCH DATA: PRIVACY AND CONFIDENTIALITY

Summary by Hannah Khader Sakalla, Taylor Broadbent, Megan Glasmann & Tanner Matthews

- **Kayte Spector-Bagdady**, J.D., M.Bioethics, Assistant Professor, Chief, Research Ethics Service, University of Michigan Medical School
- **W. Nicholson Price II**, J.D., Ph.D., Professor, University of Michigan Law School
- **Leslie E. Wolf**, J.D., M.P.H., Interim Dean and Professor, Georgia State University School of Law
- Moderator: **Teneille Brown**, J.D., Professor of Law, Adjunct Professor Internal Medicine, University of Utah

The symposium's first panel addressed issues of privacy and confidentiality, including legal and ethical restrictions on sharing medical research data. The panelists also discussed new and exciting uses of research data such as the application of artificial intelligence ("AI") to health information.

Kayte Spector-Bagdady discussed the legal tensions in health data procurement and use. Her presentation began with an overview of how health data is governed. Spector-Bagdady observed that we govern health data and specimen collection generally through HIPAA if the data is identifiable, but through the

Common Rule for some research with identifiable data, and through regulatory bodies if the data is collected for commercial purposes. Spector-Bagdady then argued that what patients and participants who are providing this data care about is how their data is used after its collection—not how it is procured. Many data contributors expect that researchers will formally obtain their consent for specific research purposes and data contributors express varying levels of comfort with who is using their data (if it is sold) and why. Spector-Bagdady suggested that regardless of how data is procured, health data is eventually used for similar purposes.

Spector-Bagdady also suggested that regulatory mechanisms have, so far, failed to improve participant understanding of the research process. There continues to be a tension between how we govern health data and specimen collection and what contributors really care about, which is how their data is used. Should we be concerned if data contributors would be less likely to give consent if they knew their data would be used for commercial purposes or for "controversial research purposes"? Or should we accept this tension because health data and specimen collection is incredibly valuable and lucrative as it currently functions? Assuming that we do care about resolving this tension, Spector-Bagdady suggested that academic medical centers can hold themselves accountable to higher standards than regulation requires. She highlighted the importance of providers having a conversation with contributors, as many are unlikely to read a twenty-page informed consent document that outlines health data use. Additionally, she suggested that academic journals should set higher standards to encourage a "rising tide that lifts all boats" toward improved contributor comprehension.

W. Nicholson Price II focused his comments on two related questions: (1) how does AI change how we think about privacy and restrictions on medical data, and (2) how do privacy rules and consent rules impact the way that medical AI develops, is trained, learns, and performs? Price argued that, in general, AI is making existing privacy rules and consent rules weaker than we might otherwise think. This is due, in part, to the ability to reconnect de-identified medical records with non-protected personally identifiable records in many commercial contexts. Price observed that some people may focus on the erosion of privacy and consent, with little concern for the impact of privacy rules and consent rules on the way medical AI develops.

Price, however, contended that the impact on medical AI development is important. He argued that existing privacy protections are a burdensome hurdle to academics and non-profits attempting to create data sets to train medical AI. As a result of the high cost of compliance with consent rules, medical AI systems developed by these groups tend to be based on data sets generated by high-resource health centers. But high-resource health centers often do not serve diverse communities, so, in some circumstances, AI systems are being trained on incomplete, non-representative, and biased data. Price believes that academic and non-profit research organizations are more likely than commercial enterprises to produce valuable research based on medical AI. Despite the generally high quality of medical technologies and care recommendations produced by these groups, the technologies and recommendations resulting from medical AI research may be of

lower quality than would otherwise be possible because of bias in the data sets used to train the AI.

Price has not found an easy solution to this dilemma of how to protect privacy and respect consent while fostering advances in medical research using AI. He finds it difficult to justify tightening privacy rules and consent rules, which may negatively impact valuable research done by academics and non-profits. However, he also recognizes that socially privileged groups are less worried than more vulnerable communities about the downstream consequences of making private medical records public. Price acknowledged that maintaining current privacy protections and consent requirements in research may be valuable, even when commercial interests may be able to use AI to shortcut those rules.

Leslie E. Wolf focused her comments on the purpose of Certificates of Confidentiality and potential gaps in confidentiality protections for research participants even after the passage of the 21st Century Cures Act in 2016. Wolf began by discussing the historical background of Certificates, which were first adopted in 1970 to facilitate research on illegal drug use and shield participants from the risk of felony prosecution during the national War on Drugs. The core protection of a Certificate of Confidentiality is that a research participant's identifiable, sensitive data may not be obtained by subpoena or court order for use in a legal proceeding. The Certificates program was later expanded to cover other sensitive research subjects, such as HIV and human genetics. The current scope of the program includes all research that falls under the umbrellas of biomedical, behavioral, and clinical research, including mental health and substance use (e.g., alcohol and psychoactive drugs) research.

Wolf noted that Certificates only apply to research; they do not apply to commercial databases. She outlined the legal requirements for mandatory issue and automatic issue of Certificates, and discussed when applications for Certificates may be denied. Wolf also explained that Certificate protections extend to all copies of covered data in perpetuity. Additionally, Wolf discussed the limited exceptions for when researchers may disclose identifiable information that is protected by a Certificate. Historically, disclosure could occur voluntarily to report communicable diseases, abuse, or harm to self or others; this is no longer the case after amendments to the federal law governing Certificates. The current exceptions for disclosure include the following: (a) with individual consent, (b) for medical treatment with individual consent, (c) for research purposes (if the research complies with federal regulations for research), or (d) as required by federal, state, and local law (excluding instances of compelled disclosure in a legal proceeding).

In her discussion of potential gaps in Certificate confidentiality protections under the Cures Act, Wolf raised the issue of how Certificate protections operate when research data is included in the electronic health record used for clinical care of a research participant. This means that parts of a clinical care health record may be protected by a Certificate. Wolf questions who will know or remember that this data should be treated differently if the electronic medical record is subpoenaed?

Another concern for Wolf is the application of varying state mandatory reporting laws to participant research data protected by Certificates. A pregnant

woman participating in a substance use study might lose future custody of her unborn child if a toxicology report comes back positive in a state where the researcher must report her to child protective services. Likewise, a man participating in a study that includes a cognitive evaluation may lose his driver's license if he lives in a state where physician-researchers are mandatory reporters of conditions that may impair participants' ability to drive safely. There are clear ethical concerns at play when disclosure of research data may harm participants' lives in such significant ways. Wolf concluded her remarks by emphasizing that while the 21st Century Cures Act made several beneficial and important changes to the Certificates statute, there remain gaps in Certificate protections that may undermine participant trust.

After the panelists finished their presentations, **Teneille Brown** conducted a Q&A session based on questions submitted by audience members. In response to a question about declining enrollment in clinical trials as a result of doing more to inform participants about the range of uses that could be made of their data, Spector-Bagdady said there had indeed been a decrease in study enrollment at her institution, the University of Michigan, after it adopted these practices. However, it was unclear to her whether the decline was substantial enough to impede the research being done there. In addition, she shared that the University of Michigan is undertaking a process of reflection with the aim of becoming more responsive to the concerns of communities of color and developing a consent process that is more welcoming and trustworthy for those communities. Brown commented that this provides a great example for other institutions.

Another questioner asked the panelists to discuss transparency in health data sharing arrangements in light of a story reported in the *Wall Street Journal* about confidential contracts between Google and large US health systems. Wolf explained that many uses of data that make people uncomfortable are entirely legal. She suggested that there should be more efforts to be explicit about what is done with people's data and the benefits to society that can flow from the use of their data. In the same vein, Price emphasized that the use of health data for research involves a grand bargain: It makes medical care better, but it requires accepting reduced privacy in our health information. He agreed that more should be done to articulate the benefits alongside the risks.

Expanding on their comments, Brown drew an analogy between a student's perception of adjunct and tenure-track faculty and the average person's perception of the various entities that collect health data. Just as the differences between adjunct and tenure-track faculty are not salient for the typical student, when it comes to the uses to which their health data is put, patients and consumers may not adequately distinguish between academic researchers and a private sponsor of research connected tangentially to their personal doctor at an academic medical center. For Brown, this further underscored the importance of communicating with the public to build more trust.

CLINICAL TRIALS – LEGAL AND ETHICAL ISSUES IN THE AGE OF COVID-19

Summary by Karthik Sonty, Kaitlynn Morgan, Niki Crabtree, Ellie Bradley, Nicole Redmond, Nicole Johnston & Morgan Tingey

- **Dr. Michael Dean**, M.D., M.B.A., Professor and Vice-Chairman for Research, Department of Pediatrics, University of Utah School of Medicine
- **Erin Rothwell**, Ph.D., Associate Vice President for Research, Office of Research Integrity and Compliance; Professor, Department of OB/GYN, School of Medicine, University of Utah
- **Seema K. Shah**, J.D., Founders' Board Professor of Medical Ethics, Associate Professor of Pediatrics (Academic General Pediatrics and Primary Care), Northwestern University School of Medicine and School of Law
- **Ana Santos Rutschman**, J.D., Assistant Professor of Law, St. Louis University School of Law
- Moderator: **Dr. Willard H. Dere**, M.D., F.A.C.P., Associate Vice President for Research, Professor of Internal Medicine, University of Utah Health Sciences

Dr. Willard H. Dere opened the panel by describing our current reality in the COVID-19 pandemic. On the day of the symposium, over 11 million Americans had been diagnosed with COVID-19, resulting in over 250,000 deaths. Dr. Dere emphasized the unprecedented partnerships that have been developed between the public and private spheres to facilitate rapid clinical trials, create messenger RNA patents, develop vaccines, and test medications on patients in the field. Dr. Dere framed the panel as a discussion of ethical and legal issues as they relate to the breadth of these clinical research activities, specifically focused on clinical trials during this pandemic.

Dr. Michael Dean's presentation gave a brief overview of clinical trials and explained key terms surrounding clinical research and COVID-19 research. Dr. Dean explained that clinical research includes any research that involves patients or humans, regardless of whether the trial is testing a new drug or device. Some clinical research studies are not interventional and can be done without encountering a patient. Notably, there is an ethical question about whether the pandemic is crowding out non-COVID-19 clinical research. Due to a shortage of PPE at the beginning of the COVID-19 pandemic, nearly all clinical research at the University of Utah stopped. However, given the research demonstrating that participation in clinical research trials confers a benefit to patients, this raises the question of whether it is ethical to stop non-COVID-19 clinical research.

There is a variety of common interventions for patients with COVID-19. One of the most common is the antiviral medication Remdesivir, which was approved for use based on a trial that many people believe was stopped prematurely. Another intervention is convalescent serum. The process for this intervention consists of

obtaining serum from individuals with COVID-19 antibodies and then administering the serum to other individuals. Numerous ongoing trials are utilizing convalescent serum. Dexamethasone is a steroid that is also used for COVID-19. Patients with COVID-19 who experience clotting or thrombosis are commonly placed on antithrombotic drugs. Hydroxychloroquine is an anti-malarial drug used in a variety of rheumatic diseases. The use of hydroxychloroquine became very politicized, which may have limited the investigation of this drug in a more scientific manner. The last common intervention for patients with COVID-19 is vaccines.

Erin Rothwell's presentation provided an overview of ethical foundations for clinical research and the emerging ethical issues brought to light during the COVID-19 pandemic. Rothwell detailed the history of ethical foundations for clinical research in the United States. The goal of clinical research is to develop generalizable knowledge for future patients, which is used to develop new treatments and protocols for managing specific diseases and care. Clinical trials are critical to creating the evidence base for future medical decision making. However, there are numerous ethical issues with many trials, including no contribution of meaningful data to the evidence base and uninformed patient consent.

Many ethical issues were present before the pandemic but were magnified by the pandemic. The pandemic forced institutions to make quick decisions about clinical research studies while under immense public pressure to discover treatments for COVID-19. This tension highlighted weaknesses in the conduct of clinical trials in general, especially for informed consent. Rothwell stated that informed consent is not effective in promoting informed decision making. Current informed consent processes cause confusion for patients and prevent equitable access for non-English speakers, which creates an imbalanced population sample. Rothwell stressed that reliance on the informed consent process to communicate protection of individual rights in medical research is insufficient to constitute ethical behavior in clinical trials.

Rothwell discussed her experience with a therapeutic panel at the University of Utah, whose goal was to categorize COVID-19 trials. At the University of Utah, there was a small number of COVID-19 patients in the ICU, but a large number of trials trying to recruit these patients. Because of the exclusionary nature of COVID-19 trials, researchers were forced to choose which trial to place a patient into without knowing which was the most effective intervention. Additionally, each patient not in a trial was considered a missed opportunity to discover the best intervention for future patients. The committee's goal was to categorize potential COVID-19 trials into top tier, middle tier, and lower tier. The therapeutic panel came up with 10 questions to prioritize COVID-19 trials, including identifying whether the trial was sponsored and if the trial was well-controlled. For Rothwell, this approach represents a new age of informed consent in which researchers think in innovative ways about providing information about studies.

Seema K. Shah discussed the potential role—and associated ethical considerations—of Controlled Human Infection studies ("CHIs") to accelerate and improve the development of a COVID-19 vaccine. CHIs deliberately expose participants to the pathogen in question so that individual responses to the disease,

vaccine, and placebo can be closely controlled and studied. CHIs can be used as an alternative to, or in tandem with, clinical trials as part of a traditional tri-phase vaccine development pathway. When seeking to accelerate vaccine timelines, ethical concerns surrounding CHIs generally favor the use of expediting clinical trials, compressing phases, or conducting phases in parallel. Vaccine availability can also be expedited via Emergency Use Authorization which streamlines the regulatory review submission process and lowers the efficacy threshold required for the Food and Drug Administration to authorize use. Even with these measures in place, the rapid and widespread global impact of COVID-19 has renewed interest in finding a role for CHIs in vaccine development while also balancing ethical concerns.

Prior to the pandemic, Shah and her colleagues had developed a comprehensive ethical framework of analysis for CHIs and rapidly repurposed it for COVID-19 focusing on two of the framework's seven components: (1) the requirement for sufficient social value and (2) a reasonable risk-benefit profile. First, a study's social value is measured by analyzing the magnitude of the study's likely health benefits. Since COVID-19 is a high-risk virus, there must be a clear connection between the CHIs and health benefits. Shah suggests that COVID-19 CHIs could exceed the social value threshold by identifying correlates of protection that would prove useful for future vaccine research, helping prioritize vaccine formulas among more than 200 candidates, or by helping identify second generation vaccines more quickly. Second, to create a reasonable risk-benefit profile, risks and benefits to participants must be systematically identified, evaluated, and minimized. In COVID-19 CHIs, risks could be minimized by enrolling young, healthy adult participants and monitoring them closely. However, unknowns regarding long-term complications of COVID-19 and lack of treatment for severe complications significantly increase potential CHIs risk. Public trust also plays a role and must be secured prior to conducting CHIs. Ultimately the social value and risk of CHIs for COVID-19 are dynamic and worth evaluating, but it is uncertain whether or not they are ethically justified.

Ana Santos Rutschman discussed clinical trial data, using COVID-19 vaccine trials to examine challenges in the way clinical trial data is collected and regulated. One of those challenges is the under-representation of minority and low-income populations in trial data. COVID-19 vaccine trials conducted by Pfizer and Moderna sought 26 and 24 percent diversity rates, respectively. Each of these targets falls roughly 20 percent below the actual diversity of the U.S. population. This shortcoming isn't limited to COVID-19 trials, but reflects a long-term problem in how participants are enrolled in clinical trials.

Rutschman also explained that the rush to make a COVID-19 vaccine widely available has underscored the importance of transparent and accessible clinical trial data. Vaccine developers are seeking approval through a regulatory pathway called Emergency Use Authorization, which lowers the threshold for the quality of clinical data normally required to approve a vaccine for market use. While the COVID-19 vaccine trials have shown high efficacy of the vaccines tested, participants have predominantly been healthy adults. This raises questions about safety and efficacy

for population subgroups like the elderly, people with comorbidities, and various racial and ethnic subgroups.

Access to complete clinical data is essential in order for other researchers to expand the body of knowledge regarding COVID-19 vaccines; however, the Food and Drug Administration has a history of interpreting data-sharing policies in a manner that makes it difficult for other researchers to add to the findings. In 2007, Congress mandated more comprehensive reporting of clinical trials, but greater transparency is still needed to facilitate follow-on research.

Once the panelists concluded their presentations, **Dr. Willard Dere** led a Q&A session with questions submitted by the audience. An audience member requested that Shah discuss context-specific community engagement, one of the seven components of Shah's ethical framework for CHIs. Shah explained that the method of community engagement should be tailored to the reason for the engagement. In the current COVID-19 pandemic, the most important reason for community engagement has been to further public trust, which can be eroded by rumors about vaccine trials. As an example of excellent community engagement, Shah mentioned Dorcus Kamuya's advisory board in Kenya with a bi-directional relationship of information sharing with the community. Another important medium for community engagement is social media platforms, though some believe they cannot yield fruitful interactions. However, Shah expressed confidence that experts in community engagement will be able to effectively address this issue.

In response to several questions, Dr. Dean discussed his views on the currently available interventions for COVID-19. He emphasized that the most important intervention is the vaccine. Evidence has shown them to be 95% effective, which is an unprecedented rate for new vaccines. As for the available treatments, medications such as antivirals, steroids, and antibody mixtures can be effective in different settings. Dr. Dean also discussed public confidence and whether journals should relax their standards to publish COVID-19 data faster. He supported faster distribution of research but warned against publishing data that is too preliminary because people tend to remember the data as fact even after articles are retracted. This happened with the retracted *Lancet* article stating that hydroxychloroquine was harmful as a COVID-19 treatment. Dr. Dean cautioned there may be ethical issues when journals rush to publish new data before their competitors and end up publishing incorrect information that misleads the public.

Dr. Dere concluded by urging that, given the vaccine data and benefit-risk profile, the audience should strongly consider getting one of the COVID-19 vaccines that the FDA has been carefully reviewing.

INTELLECTUAL PROPERTY AND MEDICAL RESEARCH

Summary by Connor Nelson, Emily Haynie, Richard Poll, Victoria Countryman, Brooke Porter Coles & Aisea Odencrantz

- **Clark D. Asay**, J.D., Professor, BYU School of Law
- **Stephanie Plamondon Bair**, J.D., Ph.D., Associate Professor, BYU School of Law
- **Michael B. Eisen**, Ph.D., Adjunct Professor of Genetics and Development, UC-Berkeley; Investigator, Howard Hughes Medical Institute
- **Jenny Molloy**, Ph.D., Founder and Director of the Open Bioeconomy Lab; Shuttleworth Foundation Research Fellow in the Department of Chemical Engineering and Biotechnology at the University of Cambridge
- **Diane Peters**, J.D., General Counsel and Corporate Secretary, Creative Commons
- Moderator: **Jorge L. Contreras**, J.D., Presidential Scholar and Professor of Law, University of Utah

Intellectual property (IP) protections drive value in many sectors of the modern economy. Intellectual property law's periods of exclusive rights generate some of that value. While in the term of protection, no other entity may legally create the rightsholder's protected IP without the rightsholder's permission. The rightsholder thus benefits economically from the resulting limited monopoly. However, that protected IP also possesses inherent value for society; inventions and creations serve previously unaddressed or inadequately addressed needs. Furthermore, other creators can and often must use protected IP to make further discoveries in their respective fields. With robust and regularly enforced IP protection, subsequent innovation becomes more difficult as cutting-edge knowledge remains inaccessible to other creators for long periods. The COVID-19 pandemic has cast this dynamic in an urgent light. New diagnostic tests, medical equipment, and vaccines represent significant research and production investment for the companies producing them. However, communities immediately require these tools to save lives. These issues also have an international dynamic, where countries that need protected IP for their populations may not have the resources to afford it.

In light of these concerns, the Intellectual Property and Medical Research panel focused on addressing two questions related to medical IP: (1) how to spark innovation through the exclusive grant that intellectual property bestows, and (2) how to responsibly deal with the exclusivity that intellectual property protections create. The panelists explored the complexities of these questions and their influence on innovative processes. They also promoted solutions where rightsholders participate in open IP sharing organizations, such as the Open COVID Pledge. IP sharing aims to make protected IP accessible for other creators' use without leveraging intellectual property law's exclusivity for their profit.

Clark Asay and Plamondon Bair explored the relationship between adversity and innovation in order to better structure intellectual property and research incentives to respond to public health challenges. Their work draws on psychology, sociology, organizational behavior, and neuroscience to determine which patterns and characteristics of adversity are either detrimental or conducive to innovation. Among their findings was a "Goldilocks" relationship between adversity and innovation—inspiration occurred least at either extreme of adversity's duration, breadth, and intensity. Their findings have important implications for incentivizing innovation to respond to challenges such as the COVID-19 pandemic.

Asay and Plamondon Bair assessed multiple methods of structuring intellectual property to best encourage innovation during adverse events. Their research suggests market-based mechanisms and patent rights may not be conducive to innovation in all adverse circumstances. They explored the potential of government funding as an alternative spur to innovation. Where technological path dependencies emerge (such as the industry-wide focus on COVID-19 vaccines and therapies), Asay and Plamondon Bair suggested that the patent market may not be an efficient mechanism for facing adversity.

Michael Eisen shared his experience with the importance of intellectual property, particularly patents, throughout his career. As a young graduate student, he remembers rarely thinking about patents. However, thirty years later, he describes daily life affected "almost entirely in a negative way" by intellectual property rights. He claims intellectual property slows the work performed in research labs and increases their costs. Every day, researchers must create methods to work around patents, worry about material transfer agreements with other researchers, and write memos to their technology transfer departments about patenting minor method modifications. Every researcher, including graduate students, thinks about the commercialization and patentability of their work. Eisen labels intellectual property rights as a "tax" levied against researchers. This tax is two-fold: indirect costs from increases in the time cost of research and direct costs such as legal costs and licensing fees. He tells of a cycle where intellectual property leaves universities, goes to companies, and is licensed back to research labs at a premium.

At the outset of the COVID-19 pandemic, Eisen wanted to find a way to incentivize researchers in academia to use their specialties and skills to address the disease. From the first meeting of researchers and faculty within the UC-Berkeley community, the topic of patents arose. The conversation not only asked about navigating the current intellectual property playing field but also asked how UC-Berkeley could patent its work product. His frustrations with the barriers created by intellectual property in developing and deploying cures to all diseases led him to the Open COVID Pledge. He hopes the Pledge will serve as an instructive example to change the research obstacles imposed by intellectual property going forward.

Jenny Molloy focused her remarks at this symposium panel on what it is like being inside of an academic institution and dealing with intellectual property as a barrier, especially in international research contexts. She works closely with collaborators in Africa and Latin America to develop the manufacturing of basic research tools through a combination of molecular biology and engineering

techniques. Molloy pointed out that the many misunderstandings about how patents work unfortunately limit the use of open technologies.

Molloy highlighted that knowing and using what is already in the public domain is an important tool at the disposal of researchers. She is raising awareness of the importance of having very clear and obvious mechanisms for documenting and describing what others can do with a particular piece of technology. The theme of her message at this panel was the need for clarity within intellectual property protections, especially using licenses to be clear whether people can take a piece of innovation and build on and commercialize it. In addressing a question about what role lawyers play in helping provide clarity on intellectual property issues, Molloy had this message: "keep working on the tools because we still need them."

Molloy also spoke about the Open COVID Pledge, a commitment that researchers and companies can make to share their intellectual property for the purposes of mitigating and ending the COVID-19 pandemic. She shared that a major advantage of a pledge to be open with intellectual property during the current global health crisis is that private entities can act with speed and agility that governments cannot. Molloy also expressed that she views the Open COVID Pledge as only one piece in a much bigger puzzle needed to make technology useful.

Diane Peters helped to develop and steward the Open COVID Pledge. She explained that there are two extreme approaches to intellectual property. On one end of the spectrum, companies and individuals reserve all of their IP rights. On the other end sits a requirement that everything remains open and available. The Open COVID Pledge is one solution among many that fall within this spectrum. The pledge includes a simple statement of commitment that holders of IP rights won't assert that right against others. The pledge creators intentionally made it simple, easy, and internationally robust. The Open COVID Pledge creators, including Peters, were overwhelmed by the positive response of companies.

In addition to the public statement of commitments, the Open COVID Pledge has underlying licenses or compatible and alternative licenses. These licenses allow researchers to use IP produced by others with the assurance that they are available under basic and consistent terms. Additionally, the licenses work to address the concerns brought up by other panelists that IP blocks research.

The Open COVID Pledge creators did not intend it to be the only solution but rather a voluntary private option. There are other answers, such as governments mandating that companies relinquish their rights. But Peters emphasized the importance of remembering that tax dollars in every country are going toward solutions to the pandemic, and governments must be accountable for what they fund. She said some companies might find the pledge attractive because they are terrified that governments will force them to give up their IP rights to COVID-19 solutions.

Peters highlighted that many crises are coming beyond the COVID-19 pandemic, like the global climate crisis. The current pandemic is a unique moment in history, and we must seize upon it to change minds and directions within IP. Her goal is to make it as easy as possible for researchers to do their work. Peters believes we should address these issues at an international level because that is where "basic

infrastructure change" at a legal level takes place. She also encouraged involvement at a federal level in the United States.

Following the conclusion of the panelists' remarks, **Jorge Contreras** asked the panel to comment on how the goals of the Open COVID-19 Pledge, a private initiative, could be achieved through public policy. Plamondon Bair noted that the central psychological force that drove the creation and current success of the Pledge was the need to collaborate and share amongst private actors, and that with the force of individual motivation, government intervention may not be necessary. Eisen expanded upon Plamondon Bair's thoughts by noting that current government funding to academic institutions created many roadblocks to innovation and that he hoped to see the United States government look to the Pledge as an example for effective IP policy. Peters added that the current COVID-19 pandemic is not the last pandemic or global crisis the world will face, noting specifically the global climate crisis, and that her hope was for lawmakers to see the Pledge and its goals of collaboration for the public good as a stepping stone to solving future problems.

Turning the discussion to the impact of current legislation on the academic research environment, Asay noted that the current mindset of walking into research with patents in mind has dramatically impacted the type and function of the research and development being conducted. Molloy commented that the various costs, speed of processing, and clarity of the current patent and intellectual property process through various government entities have always created major obstacles. She observed that the Pledge has facilitated smoother and faster transactions of information, leading to rapid advancements in the development of vaccines and therapies for COVID-19.

Contreras followed up by inquiring about panelists' policy suggestions for the Biden administration regarding intellectual property rights. Eisen hoped to see a comprehensive conversation about the way the government currently treats intellectual property and funds allocated to it, and how legislation could be altered to be best for innovation as a common goal. Peters echoed Eisen and noted that many foundations are heavy funding contributors to various research institutions so any changes to the government's focus should apply to foundations as well. Additionally, she hopes to see periodic reviews of government policy to evaluate if the original goals of the legislation have been met and to analyze what improvements might be made. Plamondon Bair added that the Bayh-Dole Act has encouraged research institutions to focus on technology that is immediately commercializable and that this has, in turn, led to a decreased sharing culture among researchers.

In response to a question from the audience, the panelists discussed the role of lawyers in the future of intellectual property and sharing new technology in the spirit of the Open COVID Pledge. Molloy noted that while there are a growing number of legal tools that are free for technology companies and individuals to access, a lack of standardization among the tools decreases their effectiveness and usefulness. Eisen built on that point, noting that many material transfer agreements differ by jurisdiction and that there is a constant addition of clauses depending on the university, research institution, or other entity, which also does not help streamline the process. Asay encouraged aspiring and current attorneys in the intellectual

property space to become familiar with new legal tools in order to help their clients in the long-term and to not stay stuck in current practices of an industry.

To wrap up the discussion, Contreras asked the panel to think about the future and what the COVID-19 pandemic has taught the world about intellectual property. Peters stated that more voices are needed to push progress on access, speed, and collaboration in intellectual property at the international level. She noted that the goal of the Pledge should apply to intellectual property rights and public policy moving forward—that is, making it as easy as possible for researchers to do what they do best. Eisen agreed with the need to use a larger effort with more voices to push for more open sharing and innovation across the board, particularly as he had witnessed the pushback from various entities to limit the scope and application of the Pledge. Molloy explained that the Pledge made a new option available to people and that she hoped this would establish a positive precedent moving into the future. Asay concluded that open source software had a similar starting point, and he hoped intellectual property rights in medical research could have similar positive outcomes.

MEDICAL RESEARCH AS A PUBLIC HEALTH INITIATIVE

Summary by Darian Hackney, Sandra Sulzer, Emily McKay & Ryan Anderson

- **Heather Tanana**, J.D., M.P.H., Assistant Professor of Law (Research) and Wallace Stegner Center Fellow, University of Utah
- **Jennifer K. Wagner**, J.D., Ph.D., Associate Director and Assistant Professor, Geisinger
- **Wendy Parmet**, J.D., Matthews Distinguished University Professor of Law; Director, Program on Health Policy & Law, Northeastern University School of Public Policy and Urban Affairs
- Joining for Q&A: **Jeremy Paul**, J.D., Professor of Law and former Dean, Northeastern University School of Law
- Moderator: **Tammy M. Frisby**, Ph.D., Executive Symposium Editor, *Utah Law Review*

Each of the panelists brought a different approach to a set of common questions. First, how do medical research and the way we communicate about research and data influence trust in medical research and, more broadly, efforts to protect and improve public health? Second, where has the law failed to protect trust, and how might the law be reformed in order to improve and advance public health?

Heather Tanana discussed medical research in tribal communities. Tanana, a member of the Navajo Nation, provided a historical framework for understanding the distrust native communities feel toward the government, especially regarding medical treatment. Although the COVID-19 pandemic has disproportionately impacted native populations, indigenous communities have responded to the promises of a vaccine with skepticism. Tanana recounted the federal government's extensive history of harming native communities under the guise of public health,

citing numerous ethical violations such as lack of informed consent, harming individuals, placing individuals at high risk of injury, failure to evaluate the risks and benefits of research, withholding effective treatment, and taking advantage of vulnerable populations.

Other drivers of distrust in native communities include lack of native-led research, underlying safety concerns related to participating in clinical trials, privacy, preservation of cultural and tribal integrity, and compensation. Tanana indicated that programs initiated within native communities and led by community members might reduce distrust. Notably, the pandemic has also presented an infrastructure problem for native communities that lack internet access, landlines, or cellphone service. These infrastructure issues created additional obstacles for communities and principal investigators attempting to provide information about COVID-19 trials to indigenous communities.

Jennifer K. Wagner observed that during the COVID-19 public health crisis, new questions have emerged about data collection policies. As the pandemic has unfolded, healthcare and public enterprises have been trying to transcend boundaries that have traditionally divided their approach to data management. As a result, precision medicine and precision public health have collided. The biomedical field has high respect for individual autonomy and an "opt-in" policy, whereas the field of public health puts an emphasis on justice, solidarity, and an "opt-out" policy. Patients receiving medical care must explicitly consent to have their data shared or used. But in public health settings, universal information sharing is the norm and expectation to promote effective epidemiology. Communities cannot know the total number of mortalities, or positive test cases, when only some individuals opt-in.

Wagner also noted that as research infrastructure is leveraged for non-research, COVID-19 purposes, new ethical questions have emerged. Who has the right to restructure our data collection mechanisms, policies, and infrastructure? When, how, and to what extent? And ultimately, who is accountable for data security and other considerations? Disclosure of COVID-19 data could have ramifications for patients. And Wagner emphasized that the field of data valence can provide insights into the rhetorical and oppressive manners in which this data can be used. Data valence is an international human rights concern, especially how information gathered in the context of the pandemic could lead to rights violations. As we proceed through this pressing public health crisis, it is crucial we keep these rights at the forefront of our considerations.

Wendy Parmet addressed the "infodemic," a term coined by the World Health Organization that pertains to the overabundance of misinformation regarding the COVID-19 pandemic. The key distinction between the infodemic and the past spread of general misinformation is the role that law has played in affecting public trust in biomedical research. In response to this infodemic, Parmet proposes a recalibration of health law and a cultural shift that provides greater weight for expertise and greater accountability for public harms.

Parmet explained that the infodemic is rooted in the rise of epistemological nihilism, in which science has lost its authority due to a form of radical subjectivity where one's own feelings and impressions become the standard for one's judgment.

Although health law has not caused the infodemic, it has unintentionally supported and enabled the infodemic by prioritizing patient autonomy and subjectivity.

Our current health law, broadly speaking, prioritizes individual choice over individual responsibility for the well-being of others. As individual authority has increased, respect for expertise has eroded. This shift is evident throughout a variety of Supreme Court opinions and legal doctrines. For example, the Supreme Court's shift to view the Commercial Speech Doctrine in a speaker-focused manner has allowed for the proliferation of direct-to-consumer advertisements. This form of advertising, along with a "Wild West" of misinformation about health allows patients to be, in essence, their own gatekeepers to prescription drugs.

Further, the holding in *National Federation of Independent Business v. Sebelius* enshrines individual choice by preventing the government from requiring individuals to take certain actions per the Commerce Clause. In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court enshrined the idea of an individual opt out, in this case for the Affordable Care Act. This "opt out" holding has created a world in which individual choice is supreme, even if an individual's choice impacts the healthcare options available to others. This shift was particularly apparent in the COVID-19 pandemic, where individual choice regarding mask wearing and vaccination became the final judge of pandemic policy.

Despite the challenges presented above, Parmet acknowledges that health experts need to earn the public's trust. There are important reasons, including protections of the vulnerable, for the move towards individual authority and individual choice. However, the question that Parmet asks society to begin to consider is this: has health law moved too far in the direction of supporting subjectivity? Parmet argues that the current approach to health law that developed to prevent the exploitation of the vulnerable, is, in fact, reinforcing vulnerability because vulnerable populations are harmed the most by this shift in public health nihilism and the infodemic.

While the submitted questions during the Q&A varied in their scope and area of public health focus, they each shared an underlying issue – the increasing lack of societal trust in U.S. institutions and science.

Parmet was asked what could be done to fight the "info-demic" of commercial, ideological speech that serves to mislead. She replied that after the *NIFLA v. Becerra* decision by the Supreme Court in 2018, the government is effectively prevented from regulating commercial speech that touches on any controversial issue – even if that regulation simply requires that the commercial speech also include true, basic, information. Parmet posited that this may be pushing public health agencies away from regulation through the dissemination of public information and towards the mandatory regulations seen in the pandemic, despite the tremendous public resistance.

Moderator **Tammy Frisby** then asked Wagner and Tanana what can be done to remedy the public's caution and distrust of the government's actions regarding vaccines and medical data privacy. Tanana addressed the question first, stating that the reason for the distrust of the federal government among her native American community was rooted in its failure to uphold promises and legal responsibilities

made to the more than 500 Native American tribes. Changing this attitude, according to Tanana, could start with the federal government following the instructions of the Supreme Court and upholding all its treaty-bound responsibilities. Wagner added that we are now seeing the applicability of the "Deception Doctrine" to issues of trust surrounding informed consent and misinformation. According to Wagner, the doctrine asserts that the failure to communicate with the consumer on their level or to clarify their misperceptions is a deception. However, the doctrine isn't a panacea to issues with trust and informed consent, said Wagner. An informed citizenry made through our educational system is the best solution.