MINNESOTA LAW REVIEW'S 2017 SYMPOSIUM

A Prescription for Pharmaceutical's Future: Balancing Industry & Consumer Concerns for Pharmaceutical Drug Development

FRIDAY, OCTOBER 27, 2017
8:15–4:00 PM

ROOM 25, MONDALE HALL
UNIVERSITY OF MINNESOTA LAW SCHOOL

PROGRAM

PROGRAM

7:30 AM: Registration and coffee

8:15 AM: **Welcome and Opening Remarks**
Caroline E. Bressman, Symposium Articles Editor, *Minnesota Law Review* Vol. 102

Devin T. Driscoll, Editor-in-Chief, *Minnesota Law Review* Vol. 102

The Dean's Office, University of Minnesota Law School

8:30 AM: **Introduction by Michelle M. Mello**, Ph.D., J.D., Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Stanford University School of Medicine

Why Ensuring Access to Affordable Drugs Is the Hardest Problem in Health Policy

8:50 AM: **Address by Joanne Chan**, J.D., Assistant General Counsel, Pharmaceutical Research and Manufacturers of America

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9:10 AM: **PANEL 1: Investigating the Pricing Equation: A Law and Economics Analysis**

Featuring:

Arti K. Rai, J.D., Elvin R. Latty Professor of Law, Duke University Law School
Regulatory Gaming and Antitrust: Drugs vs. Biologics

Christopher Robertson, Ph.D., J.D., Professor of Law and Associate Dean for Research and Innovation, University of Arizona College of Law
The Economics and Experience of Patient Cost Exposure

Rachel Sachs, M.P.H., J.D., Associate Professor of Law, Washington University School of Law
The Role of Reimbursement

Stephen W. Schondelmeyer, PharmD, Ph.D., Professor and Head of the Department of Pharmaceutical Care and Health Systems, and Director of the PRIME Institute, University of Minnesota
The Pharmaceutical Market: Signals of Market Failure, Finding Fixes & Focusing on the Future

Moderated by **Thomas F. Cotter**, M.S., J.D., Briggs and Morgan Professor of Law, University of Minnesota Law School

11:10–11:25 AM: Break

11:25 AM: **KEYNOTE ADDRESS from Dr. Jonathan P. Jarow**, Senior Medical Advisor to the Director of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration

FDA Regulation of Drugs and Biologics: Finding the Right Balance

12:00 PM: **Lunch**

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12:30–2:00 PM: **PANEL 2: "Safe and Effective" or "Now and Cheap"?: Finding the Right Role for the FDA**

Featuring:

Amy Kapczynski, M.A., J.D., Professor of Law and Faculty Director of the Global Health Justice Partnership, Yale Law School
Why Do We Have Pre-Market Review of Medicines? The "Precautionary" Fallacy and the FDA's Role in Information Production

Jordan Paradise, J.D., Professor of Law, Loyola Chicago School of Law
Regulatory Silence at the FDA: Impact on Drug and Biologic Competition

W. Nicholson Price II, J.D., Ph.D., Assistant Professor of Law, University of Michigan Law School
Drug Approval in a Learning Health System

Moderated by **Ralph Hall**, J.D., Professor of Practice, University of Minnesota Law School

2:00–2:15 PM: **Break**

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2:15–3:50 PM: **PANEL 3: Pharmaceuticals Around the Globe: Access and Delivery Issues for Consumers**

Featuring:

Margo Bagley, J.D., Asa Griggs Candler Professor of Law, Emory University School of Law
Making Room at the (Drug Access) Table: Is There a Place for Traditional Medicine?

James Love, Director, Knowledge Ecology International
Delinking R&D Costs, Including Incentives from Prices for Drugs and Vaccines

Jerome H. Reichman, J.D., Bunyan S. Womble Professor of Law, Duke University Law School
Compulsory Licensing of Patented Pharmaceuticals under Article 31bis of TRIPS: The Way Forward

Moderated by **Fred L. Morrison**, Ph.D., J.D., Popham, Haik, Schnobrich/ Lindquist & Vennum Professor of Law, University of Minnesota Law School

3:50–4:00 PM: **Conclusion by Ralph Hall**, J.D., Professor of Practice, University of Minnesota Law School

4:00–5:30 PM: **Reception in Auerbach Commons, University of Minnesota Law School**

BIOGRAPHIES

KEYNOTE SPEAKER

Dr. Jonathan P. Jarow, Senior Medical Advisor to the Director of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Jonathan P. Jarow is currently the senior medical advisor to the Center Director in CDER at FDA. Jonathan previously served as the director of CDER's Office of Medical Policy, chair of the Medical Policy Council, and as deputy director of the Office of Hematology and Oncology Products. He is a Board Certified Urologist and prior to joining the FDA he was in academic medicine for over 20 years. His last academic appointment was Professor of Urology, Pathology, Radiology, and Molecular Biology & Biochemistry at Johns Hopkins University where he worked for over ten years.

PRESENTERS

Michelle M. Mello, Ph.D., J.D., Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Stanford University School of Medicine

Michelle Mello is Professor of Law at Stanford Law School and Professor of Health Research and Policy at Stanford University School of Medicine. She conducts empirical research into issues at the intersection of law, ethics, and health policy. She is the author of more than 160 articles and book chapters on the medical malpractice system, medical errors and patient safety, public health law, pharmaceuticals, research ethics, obesity policy, and other topics. The recipient of a number of awards for her research, she was elected to the National Academy of Medicine (formerly called the Institute of Medicine) at the age of 40.

From 2000 to 2014, Dr. Mello was a professor at the Harvard School of Public Health, where she directed the School's Program in Law and Public Health. In 2013-14 she was a Lab Fellow at Harvard University's Edmond J. Safra Center for Ethics.

Dr. Mello teaches courses in torts and public health law. She holds a J.D. from the Yale Law School, a Ph.D. in Health Policy and Administration from the University of North Carolina at Chapel Hill, an M.Phil. from Oxford University, where she was a Marshall Scholar, and a B.A. from Stanford University.

Joanne Chan, J.D., Assistant General Counsel, Pharmaceutical Research and Manufacturers of America

Joanne Chan is an Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America (PhRMA). Prior to joining PhRMA, she was Corporate Counsel for Regulatory & Compliance at United Therapeutics Corporation and an associate at King & Spalding LLP. Joanne received a J.D. from Georgetown University Law Center, an M.P.H. from the Johns Hopkins School of Public Health, and a B.S.F.S. from Georgetown University's Walsh School of Foreign Service.

PANELISTS

Arti K. Rai, J.D., Elvin R. Latty Professor of Law, Duke University Law School

Arti Rai, Elvin R. Latty Professor of Law and co-Director, Duke Law Center for Innovation Policy, is an internationally recognized expert in intellectual property (IP) law, innovation policy, and administrative law. Rai has also taught at Harvard, Yale, and the University of Pennsylvania Law Schools. Rai's research on innovation law and policy in biotechnology, pharmaceuticals, and software has been funded by NIH, the Kauffman Foundation, and the Woodrow Wilson Center. Her numerous publications have appeared in both peer-reviewed journals and law reviews, including Science, the New England Journal of Medicine, the Journal of Legal Studies, Nature Biotechnology, and the Columbia, Georgetown, and Northwestern law reviews. She is the editor of Intellectual Property Law and Biotechnology: Critical Concepts (Edward Elgar, 2011) and the co-author of a 2012 Kauffman Foundation monograph on cost-effective health care innovation.

From 2009-2010, Rai served as the Administrator of the Office of External Affairs at the U.S. Patent and Trademark Office (USPTO). As External Affairs Administrator, Rai led policy analysis of the patent reform legislation that ultimately became the America Invents Act and worked to establish the USPTO's Office of the Chief Economist. Prior to that time, she had served on President-Elect Obama's transition team reviewing the USPTO. Prior to entering academia, Rai clerked for the Honorable Marilyn Hall Patel of the U.S. District Court for the Northern District of California; was a litigation associate at Jenner & Block (doing patent litigation as well as other litigation); and was a litigator at the Federal Programs Branch of the U.S. Department of Justice's Civil Division.

Rai regularly testifies before Congress and relevant administrative bodies on IP law and policy issues and regularly advises federal agencies on IP policy issues raised by the research that they fund. She is a member of the National Advisory Council for Human Genome Research, a public member of the Administrative Conference of the United States, and a member of the American Law Institute. Rai has also served on, or as a reviewer for, numerous National Academies of Science committees. In 2011, Rai won the World Technology Network Award for Law.

Rai graduated from Harvard College, magna cum laude, with a degree in biochemistry and history (history and science), attended Harvard Medical School for the 1987-1988 academic year, and received her J.D., cum laude, from Harvard Law School in 1991.

Christopher Robertson, Ph.D., J.D., Professor of Law and Associate Dean for Research and Innovation, University of Arizona College of Law

Christopher Robertson is Associate Dean for Research and Innovation and Professor of Law at the University of Arizona. He is affiliated faculty with the Petrie Flom Center for Health Care Policy, Bioethics and Biotechnology at Harvard. Robertson also founded the Regulatory Science Program, with support from the University's four health science colleges, to accelerate clinical and translational science and to train a new generation of regulators, lawyers, and scientists.

Professor Robertson is an expert in health law and the intersection of law and science. His research explores how the law affects decision making in domains of scientific uncertainty and misaligned incentives, which he calls "institutional epistemology." His work includes tort law, bioethics, the First Amendment, and corruption in healthcare and politics.

Robertson has co-edited two books, Nudging Health: Behavioral Economics and Health Law (2016) and Blinding as a Solution to Bias: Strengthening Biomedical Science, Forensic Science, and Law (2016). In 2018 Harvard University Press will publish his book, Paying for Ourselves: The Ethics, Economics, and Law of Cost-Sharing in Health Insurance.

Blending legal, philosophical, and empirical methods, Robertson's more than 50 articles have been published in law and peer reviewed journals including the New England Journal of Medicine; California Law Review; Cornell Law Review; NYU Law Review; Yale Journal of Health Policy, Law, and Ethics; Journal of Empirical Legal Studies; Behavioral Science Policy; Journal of Legal Analysis; and Journal of Law and Biosciences; among others. His work has appeared in national media such as Wall Street Journal, NBC News, NPR, and the Washington Post.

Robertson has received research support from the Robert Wood Johnson Foundation, the Greenwall Foundation, and the Edmond J. Safra Center for Ethics at Harvard. He leads the Law and Behavior Research Lab at the University of Arizona and is a member of the QuantLaw group. He has long served on the clinical ethics committee for the academic medical center, as peer reviewer for leading journals, and on doctoral committees in several social science fields.

At University of Arizona, Robertson launched a major new undergraduate course taught by law professors that exposed students to caselaw reasoning, legal institutions, and the College of Law faculty -- with JD students in preceptor roles. That class was a key part of what became the first BA in Law in the United States – a degree program that in its fourth year has 1,000 students in the United States and abroad. Robertson also secured funding to pioneer an online version of this course. The College is now building a major online program, including a team of digital staff, professional video studio, and dozens of online courses in development for undergraduate, masters, and JD students.

With dean Marc Miller, Robertson conducted a large scientific study to validate the Graduate Record Exam (GRE) as an alternative to the LSAT for admission to the JD program – a widely discussed innovation that has been followed by other law schools including Harvard, Northwestern, and Georgetown. Robertson and Miller also created the Distinguished Scholars

program. Robertson works with the admissions team to recruit outstanding students into the JD program, and then integrates them into the intellectual life of the College, including weekly faculty lunch workshops, for credit.

Robertson graduated magna cum laude from Harvard Law School, where he also served as a Petrie Flom fellow and lecturer. He earned a doctorate in Philosophy at Washington University in St. Louis, where he also taught bioethics. Professor Robertson has served as a visiting professor at Harvard Law School and NYU School of Law. Robertson's legal practice has focused on complex litigation involving medical and scientific disputes, and he continues to work with lawyers needing expertise in the social science of decision making and the laws regulating healthcare, science, and corruption.

Rachel E. Sachs, M.P.H., J.D., Associate Professor of Law, Washington University School of Law

Professor Rachel Sachs is a scholar of innovation policy whose work explores the interaction of intellectual property law, food and drug regulation, and health law. Her work explores problems of innovation and access, considering how law helps or hinders these problems. Professor Sachs' scholarship has or will have appeared in journals that include the Harvard Journal of Law & Technology, the University of California-Davis Law Review, the Yale Journal of Law & Technology, and the peer-reviewed Journal of Law and the Biosciences. Prior to joining the faculty, Professor Sachs was an Academic Fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics and a Lecturer in Law at Harvard Law School. She also clerked for the Hon. Richard A. Posner of the U.S. Court of Appeals for the Seventh Circuit. She received her J.D. magna cum laude from Harvard Law School and a Master of Public Health from the Harvard School of Public Health. She received her A.B. in Bioethics from Princeton University.

Stephen W. Schondelmeyer, PharmD, Ph.D., Professor and Head of the Department of Pharmaceutical Care and Health Systems, Director of the PRIME Institute, University of Minnesota

Dr. Schondelmeyer is a professor of Pharmaceutical Economics in the College of Pharmacy at the University of Minnesota where he holds the Century Mortar Club Endowed Chair in Pharmaceutical Management & Economics. Dr. Schondelmeyer is the Director of the PRIME Institute, which focuses on pharmaceutical research related to management and economics. He also serves as Head of the Department of Pharmaceutical Care & Health Systems.

Dr. Schondelmeyer's education, experience, and background provide him with a unique understanding of the complex and technical issues leading to dramatic changes in the pharmaceutical marketplace. His expertise includes pharmacy practice management, prescription drug reimbursement, drug benefit plan management, pricing patterns of the pharmaceutical industry, and pharmacoeconomics and outcomes management. His work experience has encompassed activities in practice, academia, professional associations, and state and federal government.

Dr. Schondelmeyer has conducted policy analysis in many areas such as reimbursement of prescription drugs under Medicaid, Medicare, managed care and other third party programs. He was appointed to the Prescription Drug Payment Review Commission, which served in an oversight and

advisory capacity to Congress for the now repealed Medicare Catastrophic Coverage Act of 1988 outpatient drug program. He has conducted research projects for a variety of sponsors including: the Centers for Medicare & Medicaid Services (CMS), the U.S. Government Accountability Office (GAO), the Congressional Office of Technology Assessment (OTA), the U.S. Senate Special Committee on Aging, the Food and Drug Administration (FDA), the pharmaceutical industry, and pharmacy associations.

Amy Kapczynski, M.A., J.D., Professor of Law and Faculty Director of the Global Health Justice Partnership, Yale Law School

Amy Kapczynski is a Professor of Law at Yale Law School and faculty director of the Global Health Justice Partnership. She joined the Yale Law faculty in January 2012. Her areas of research include information policy, intellectual property law, international law, and global health. Prior to coming to Yale, she taught at the University of California, Berkeley, School of Law. She also served as a law clerk to Justices Sandra Day O'Connor and Stephen G. Breyer at the U.S. Supreme Court, and to Judge Guido Calabresi on the U.S. Court of Appeals for the Second Circuit. She received her A.B. from Princeton University, M. Phil. from Cambridge University, M.A. from Queen Mary and Westfield College at University of London, and J.D. from Yale Law School.

Jordan Paradise, J.D., Professor of Law, Loyola Chicago School of Law

Jordan Paradise researches and publishes on the intersection of law, science, and technology. Her primary focus is in the life science realm, examining legal and policy issues in the development and regulation of pharmaceuticals, medical devices and innovations in medicine. Recent interests span nanotechnology, synthetic biology, precision medicine, gene editing, and electronic cigarettes. Her publications have appeared in both peer-reviewed and legal publications.

Previously, Professor Paradise served as the Schering-Plough Professor of Law at Seton Hall University School of Law in New Jersey where she was a faculty member of both the Center for Health & Pharmaceutical Law & Policy and the Gibbons Institute for Law, Science & Technology. From 2005-2009, she was the Associate Director of Research & Education for the Joint Degree Program in Law, Health & the Life Sciences and the Consortium on Law and Values in Health, Environment & the Life Sciences at the University of Minnesota Law School. She was also an adjunct associate professor of law, a research associate in the Center for Bioethics, and the faculty editor-in-chief of the Minnesota Journal of Law, Science & Technology during her time at the University of Minnesota.

W. Nicholson Price II, J.D., Ph.D., Assistant Professor of Law, University of Michigan Law School

Nicholson Price is an Assistant Professor of Law at the University of Michigan Law School. Before joining Michigan Law, he was an Assistant Professor at the University of New Hampshire School of Law. He holds a PhD in Biological Sciences and a JD, both from Columbia, and an AB from Harvard. He clerked for the Honorable Carlos T. Bea on the United States Court of Appeals for the Ninth Circuit, and was then appointed as an Academic Fellow at the Petrie-

Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Nicholson teaches patents and health law, and studies innovation in the life sciences, with a recent focus on big data and machine learning in medicine. He recommends reading Brust, Bujold, and Butcher. His work has appeared in Nature, Science, Nature Biotechnology, the Michigan Law Review, the Harvard Journal of Law and Technology, and elsewhere. Nicholson is a cofounder of Regulation and Innovation in the Biosciences and co-chair of the Junior IP Scholars Association.

Margo A. Bagley, J.D., Asa Griggs Candler Professor of Law, Emory University School of Law

Margo A. Bagley is an Asa Griggs Candler Professor of Law at Emory University School of Law. Bagley received her JD in 1996 from Emory, where she was a Robert W. Woodruff Fellow, an editor of the Emory Law Journal, and elected to Order of the Coif. She is a member of the Georgia bar and is licensed to practice before the US Patent and Trademark Office. Bagley worked as an associate with Smith, Gambrell & Russell and Finnegan, Henderson, Farabow, Garrett & Dunner before becoming an assistant professor of law at Emory University in 1999 and associate professor in 2002. She was a visiting professor of law at Washington & Lee University School of Law in fall 2001 and at the University of Virginia School of Law in fall 2005, after which she joined the University of Virginia faculty in 2006. She has also taught international patent law and related courses in China, Cuba, Germany, Israel, and Singapore. Bagley has been an occasional visiting professor at Emory Law since 2012.

Bagley served on the National Academy of Sciences Committee on University Management of Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue. She is also an expert technical advisor to the Government of Mozambique in several World Intellectual Property Organization (WIPO) matters and is the Lead Facilitator and Friend of the Chair in the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore. Bagley also was a member of the Scientific Committee of the 2013 European Policy on Intellectual Property Conference in Paris, France. Her scholarship focuses on comparative issues relating to patents and biotechnology, pharmaceuticals, and technology transfer. Bagley has published numerous articles and book chapters, as well as two books with co-authors: Bagley, Okediji and Erstling, International Patent Law & Policy (West Publishing 2013) and Patent Law in Global Perspective (Okediji and Bagley eds., Oxford University Press 2014). She also recently authored a report on Digital DNA: Synthetic Biology, Intellectual Property Treaties, and the Nagoya Protocol, commissioned by the Woodrow Wilson International Center for Scholars. A chemical engineer with a B.S. Ch.E. degree from the University of Wisconsin-Madison, Bagley worked in industry (with the Procter & Gamble Company and the Coca Cola Company) for several years before attending law school, and is a co-inventor on a patent for reduced fat peanut butter. Her courses include U.S. and international & comparative patent law, trademark law, and intellectual property.

James Love, Director, Knowledge Ecology International

James Packard Love is the Director of Knowledge Ecology International (KEI). He advises UN agencies, national governments, international and regional intergovernmental organizations and public health NGOs, and is the author of a number of articles and monographs on innovation and intellectual property rights. Knowledge Ecology International was created in 2006 as a separate entity to carry out work earlier done through the Center for Study of Responsive Law and Essential Information, where Love was employed from 1990 to 2006. Prior to that, he was Senior Economist for the Frank Russell Company, a lecturer at Rutgers University, and a researcher on international finance at Princeton University. James Love holds a Masters of Public Administration from Harvard University's Kennedy School of Government and a Masters in Public Affairs from Princeton's Woodrow Wilson School of Public and International Affairs. In 2006, Knowledge Ecology International received a MacArthur Award for Creative and Effective Institutions. In 2007, Love received the Public Knowledge IP3 award. In 2013, Love received the EFF Pioneer Award, to recognize leaders who extend freedom and innovation in the realm of information technology. In 2015, he received, with his wife Manon Ress, the Joe A. Callaway Award for Civic Courage.

Jerome H. Reichman, J.D., Bunyan S. Womble Professor of Law, Duke University Law School

Jerome H. Reichman is Bunyan S. Womble Professor of Law at Duke Law School. He has written and lectured widely on diverse aspects of intellectual property law, including comparative and international intellectual property law and the connections between intellectual property and international trade law. His articles in this area have particularly addressed the problems that developing countries face in implementing the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). On this and related themes, he and Keith Maskus have recently published a book entitled International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime

Other recent writings have focused on intellectual property rights in data; the appropriate contractual regime for online delivery of computer programs and other information goods; and on the use of liability rules to stimulate investment in innovation. His most recent articles are: "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods" (co-authored with Keith Maskus), 7 Journal of International Economic Law 279-320 (2004); "A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment" (co-authored with Paul Uhlir), 66 Law and Contemporary Problems 315-462 (2003); and Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge (with Tracy Lewis) in International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime (2005).

Professor Reichman serves as special advisor to the United States National Academies and the International Council for Science (ICSU) on the subject of legal protection for databases. He is a consultant to numerous intergovernmental and nongovernmental organizations; a member of the Board of Editors, Journal of International Economic Law; and on the Scientific Advisory Board of Il Diritto di Autore (Rome).

MODERATORS

Thomas F. Cotter, M.S., J.D., Briggs and Morgan Professor of Law, University of Minnesota Law School

Thomas F. Cotter is the Briggs and Morgan Professor of Law at the University of Minnesota Law School. He received his bachelor's and master's degrees in economics from the University of Wisconsin-Madison, and in 1987 graduated magna cum laude from the University of Wisconsin Law School, where he served as Senior Articles Editor of the Wisconsin Law Review and was elected to the Order of the Coif. From 1987-89, Cotter clerked for the Honorable Lawrence W. Pierce, United States Court of Appeals for the Second Circuit. He practiced law at Cravath, Swaine & Moore in New York City from 1988-90, and at Jenner & Block in Chicago from 1990-94. From 1994-2005, he taught at the University of Florida College of Law, where he held a University of Florida Research Foundation Professorship and directed the school's Intellectual Property Law Program. From 2005-06, he was a Professor of Law at Washington and Lee University School of Law. He joined the University of Minnesota faculty in 2006.

Professor Cotter's principal research and teaching interests are in the fields of domestic and international intellectual property law, antitrust, and law and economics. He is the author or coauthor of five books, including Patent Wars: How Patents Impact Our Daily Lives (Oxford University Press, forthcoming 2018); Trademarks, Unfair Competition, and Business Torts (with Barton Beebe, Mark A. Lemley, Peter S. Menell, and Robert P. Merges) (Wolters Kluwer 2d ed., 2016; 1st ed., 2011); Law and Economics: Positive, Normative, and Behavioral Perspectives (West 3d ed., 2013) (with Jeffrey L. Harrison); Comparative Patent Remedies: A Legal and Economic Analysis (Oxford University Press, 2013); and Intellectual Property: Economic and Legal Dimensions of Rights and Remedies (with Roger D. Blair) (Cambridge University Press 2005). Altogether he has authored or coauthored over 60 other scholarly works, including articles in the California Law Review, the Georgetown Law Journal, the Iowa Law Review, the Minnesota Law Review, and the University of Illinois Law Review. He also publishes a blog, ComparativePatentRemedies.com, on the law (both foreign and domestic) and economics of patent remedies.

Ralph F. Hall, J.D., Professor of Practice, University of Minnesota Law School

Professor Hall is a professor of practice at the University of Minnesota Law School and is a principal at Leavitt Partners, where he provides consulting services regarding FDA statutes and regulations, regulatory compliance, health care policy and legislation, and the application of those regulatory systems to the medical device industry. He is a frequent speaker on FDA regulatory issues and compliance matters and has testified a number of times before Congressional committees.

Professor Hall previously served as counsel at Faegre Baker Daniels where he provided legal services, including FDA-related matters, corporate compliance, the design and implementation of multiple cross-disciplinary, corporate legal strategies, corporate law department organization and management, and general corporate counseling. Ralph has also served as General Counsel for Guidant CRM and Chief Compliance Officer for Guidant. Prior to joining

Guidant, he was with Eli Lilly, including serving as the head of Lilly's worldwide environmental law group.

Professor Hall received his B.A. from Indiana University in 1974 and his J.D. from the University of Michigan where he was a Weymouth Kirkland Scholar. Professor Hall's interests include FDA regulation, corporate compliance and governance, negotiations and the interface between corporate practice and the academic world.

Fred L. Morrison, Ph.D., J.D., Popham Haik Schnobrich/Lindquist & Vennum Professor of Law, University of Minnesota Law School

Fred Morrison is the Popham Haik Schnobrich/Lindquist & Vennum Professor at the University of Minnesota Law School, where he teaches Constitutional Law and International Law. He has been deeply involved in the establishment and operation of the University of Minnesota's own employee health insurance program, as the founding chair and now a member of its Benefits Advisory Committee and as a member of its Administrative Working Group on Health Benefits. That insurance program provides health insurance to about 20,000 University employees and an additional 20,000 dependents.

SPECIAL THANKS TO

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SUBMIT QUESTIONS DURING THE SYMPOSIUM TO

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University of Minnesota
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A Prescription for Pharmaceutical's Future: Balancing Industry & Consumer Concerns for Pharmaceutical Drug Development

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