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Introduction: Changing Regulation of Pharmaceuticals: Issues in Pricing, Intellectual Property, Trade and Ethics

Michael S. Mireles
Pacific McGeorge School of Law, mmireles@pacific.edu

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On April 4 and 5, 2019, the University of the Pacific, McGeorge School of Law hosted an international and interdisciplinary conference titled, "Changing Regulation of Pharmaceuticals: Issues in Pricing, Intellectual Property, Trade and Ethics." The conference explored a multitude of important issues related to the cost of, access to and development of life saving and enhancing pharmaceuticals. The conference was co-organized by Professors Mike Mireles and Christopher Holman. The conference was cosponsored by Drake University Law School; Wake Forest University Law School; Texas A&M University Law School; Biotechnology Innovation Organization; Gibson Dunn; Erin Dunston (Buchanan Ingersoll & Rooney); Schinders Law (Guangzhou, China); VIT University Law School in Chennai, India; Intellectual Property Law Institute of China University of Political Science and Law; and the Novo Nordisk Foundation and University of Copenhagen's Centre for Advanced Studies in Biomedical Innovation Law.

The conference featured over 50 speakers from academia, industry and law firms, including: Abdulaziz Alkhalifa (Prince Sattam University); April Alexander (Pharmaceutical Care Management Association); Mamoun Alhamadsheh (UOP, Thomas J. Long School of Pharmacy and Health Services); Margo Bagley (Emory University School of Law); Sven Bostyn (University of Copenhagen Law School); Melissa Brand (Biotechnology Innovation Organization); Dhanay Cadillo Chandler (Turku Institute of Advanced Studies); Daniel Cahoy (Pennsylvania State University Smeal College of Business); Niraj Chaudhary (UOP); Mark Christiansen (UOP, Physician Assistant Program); Rena Conti (Boston University Questrom School of Business); Jorge Contreras (University of Utah School of Law); David Collum (UOP, Thomas J. Long School of Pharmacy and Health Services); Erin Dunston, (Buchanan, Ingersoll & Rooney); Samuel Ernst (Golden Gate University School of Law); Brian Frye (University of Kentucky Law School); Manimuthu Gandhi (VIT Law School); Leanne Gassaway (America's Health Insurance Plans); Henry Greely (Stanford University); Shelly Gulati (UOP, School of Engineering & Computer Science); Gordian Hasselblatt (CMS Hasche Sigle); Keith Hatschek (UOP, Conservatory of Music); Yaniv Heled (Georgia State University College of Law); Peter Hilsenrath (UOP, Eberhardt School of Business); Christopher Holman (UMKC Law School and Drake University Law School); Dmitry Karshtedt (The George

* Professor of Law, University of the Pacific, McGeorge School of Law.

Washington University Law School); Clark Kelso (McGeorge School of Law); Stephan Kirste (University of Salzburg Law School); Peter Lee (UC Davis King Hall School of Law); Mark Lemley (Stanford University Law School); Henry Liao (Schinders Law); Michael Malloy (McGeorge School of Law); Timo Minssen (University of Copenhagen Law School); Mike Mireles (McGeorge School of Law); Sean O'Connor (University of Washington Law School); Ruth Okediji (Harvard Law School); Emily Parento (Georgetown University Law School); Dushyant Pathak (UC Davis Venture Catalyst Office); Christopher Paulraj (USPTO); Jenny Phillips (California Department of Managed Healthcare); Pedro Pita Barros (Universidade Nova De Lisboa Business); Gary Pulsinelli (University of Tennessee Law School); Srividhya Ragavan (Texas A&M University Law School); PRL Rajavenkatesan (VIT Law School); George Randels (UOP); Simone Rose (Wake Forest University Law School); Ana Rutschman (Saint Louis University School of Law); Hans Sauer (Biotechnology Innovation Organization); Mark Schweizer (Swiss Federal Patent Court); Michael Sitzman (Gibson Dunn); Wendy Soe-McKeeman (California Association of Health Plans); Paul Subar (UOP Arthur A. Dugoni School of Dentistry); Brett Taylor (UOP, Gladys L. Benerd School of Education; Jay Thomas (Georgetown University Law School); Daniel Wadhwani (UOP, Eberhardt School of Business); Patrick Warto (University of Salzburg Law School); Timothy Welty (Drake University, College of Pharmacy and Health Sciences); Zheng Xuanyu (China University of Political Science and Law); Kojo Yelpaala (McGeorge School of Law); Liu Ying (China University of Political Science and Law); Helen Yu (University of Copenhagen) and Peter Yu (Texas A&M University Law School). The conference website contains abstracts and biographies of the speakers: https://scholarlycommons.pacific.edu/crp/.

The conference produced seven papers which are published in this issue of the University of the Pacific Law Review. The first paper is authored by Henrik Andersen (Copenhagen Business School) and titled, "WTO Law and Prices of Pharmaceutical Products: Rule of Law Gaps and the Unclear Balance between Trade Protection, Human Rights, and IP Protection." Professor Andersen explores rule of law gaps that may lead to higher pharmaceutical prices such as a lack of clarity between TRIPs and competition law, and human rights and WTO law. The second paper is authored by Samuel Ernst (Golden Gate University Law School) and titled, "The Pharmaceutical Industry's Corrupt Price Discrimination System: A Single Solution?" Professor Ernst advocates for allowing the importation of lower priced pharmaceuticals from the European Union and Canada to decrease prices in the United States or a single payer system. The third paper is authored by Christopher M. Holman (UMKC Law School and Drake University Law School) and titled, "Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection." Professor Holman challenges proposed Congressional legislation supposedly addressing the practice of patent evergreening and argues

that those proposals are generally misguided.

The fourth article is coauthored by Jonathan Kimball (Vice President for Trade and International Affairs at the Association for Accessible Medicines), Srividya Ragavan (Texas A&M University School of Law) and Sophia Vegas (Association for Accessible Medicines) and titled, "Reconsidering the Rationale for the Duration of Data Exclusivity." In that paper, the authors challenge the length of data exclusivity based on efficiencies gained by technological change. The fifth article is co-authored by Simone Rose (Wake Forest University Law School) and Tracea Rice (Fish and Richardson) and titled, "The Biosimilar Action Plan: An Effective Mechanism for Balancing Biologic Innovation and Competition in the United States?" The authors critique the Food and Drug Administration's Biosimilar Action Plan designed to increase the amount of approved biosimilars and offer some solutions to raise that number.

The sixth article is coauthored by Christopher J. Ryan, Jr. (Roger Williams University Law School and American Bar Foundation) and Brian L. Frye (University of Kentucky School of Law) and titled, "University Patents and Legal Expenditures." The authors find that an increase in patent activity by universities has resulted in a rise in legal expenses at an amount which calls into question the overall social benefit of university patenting when other behaviors are considered. The seventh paper is authored by Peter K. Yu (Texas A&M University School of Law) and titled, "China's Innovative Turn and the Changing Pharmaceutical Landscape." Professor Yu argues that policymakers dealing with China should pay close attention to regulatory changes, evolving perspectives and other developments occurring in that country.