COLUMBIA PRECISION MEDICINE INITIATIVE

PRECISION MEDICINE & SOCIETY

INTERNATIONAL PERSPECTIVES

SECOND ANNUAL CONFERENCE

MAY 7, 2020

COLUMBIA | PRECISION MEDICINE

Welcome Letter

Welcome to the second annual—virtual—Precision Medicine & Society Conference at Columbia University. Our theme this year—chosen in what now seems the distant past—is "Precision Medicine & Society: International Perspectives." We will miss the personal interaction with scholars from all over the world, but technology should permit a lively and informative dialogue.

The Precision Medicine & Society Program is an integral part of Columbia's Precision Medicine Initiative. This University-wide collaboration was created to jump-start academic discussion and research about the interplay between the biomedical advances of precision medicine and the social sciences, the humanities, law, and business. It brings together biomedical and public health researchers, clinicians, and bioethicists working at our Medical Center with social scientists, legal scholars, and humanists in the Faculty of Arts & Sciences and the Law and Business Schools.

The first annual conference, held last year, focused on issues of particular relevance to the United States. As soon as the conference had concluded, we realized that the conversations we were having, however meaningful, were too narrowly limited to the American context. To fully grasp the changes that precision medicine might entail, we needed a broader comparative framework. As societies, economies, and states differ, so do medical institutions across national boundaries.

Developed nations reflect different models of integrating precision medicine into health care. There is much to learn from how they are negotiating the ethical, regulatory, and economic issues. This year's conference is designed to compare the ways in which national healthcare systems address the challenges brought on by precision medicine.

Developing countries represent an altogether different set of challenges in this respect. In particular, there are the acute questions of whether precision medicine can be scaled up and harnessed to reduce global health disparities, and how the advances in diagnosis, targeting, and prediction in precision medicine can address the main health challenges of the developing world.

We believe that Columbia University, as a leading teaching and research institution oriented to the global dimensions of contemporary problems, is ideally positioned to lead this conversation.

Our thanks to President Bollinger, the Columbia Precision Medicine Initiative, and its director, Tom Maniatis, for supporting the Precision Medicine & Society Program and making possible this second annual conference. We hope that you will find it both enlightening and enjoyable.

Paul S. Appelbaum, MD, Elizabeth K. Dollard Professor of Psychiatry, Medicine and Law
Gil Eyal, PhD, Professor of Sociology
Co-Directors of the Columbia Precision Medicine & Society Program

Conference Schedule

PRECISION MEDICINE & SOCIETY: INTERNATIONAL PERSPECTIVES

Columbia University, New York

May 7, 2020

9:45 a.m.	Welcome and Introduction to the Conference
10:00–11:10 a.m.	**Panel: Impact on Global Health Disparities and Public Health** Gil Eyal, PhD (moderator) Donna Dickenson, PhD Sandro Galea, MD, MPH, DrPH
11:10–11:20 a.m.	Break
11:20 a.m.–12:50 p.m.	**Panel: Rolling Out Precision Medicine around the World** Maya Sabatello, LLB, PhD (moderator) China—Haidan Chen, PhD Denmark—Katharina Eva Ó Cathaoir, PhD Brazil—Jorge Alberto Bernstein Iriart, PhD
12:50–1:30 p.m.	Lunch
1:30–3:00 p.m.	**Panel: International Ethical, Regulatory, and Economic Issues in Precision Medicine** Bhavan Sampat, PhD (moderator) Ethics—Barbara Prainsack, PhD Regulation—Adrian Thorogood, BCL/LLB, LLM Economics—Patricia Danzon, PhD
3:00–3:20 p.m.	**Reflections on Precision Medicine & Society from an International Perspective** Amy Zhou, PhD

Donna Dickenson, PhD

Emeritus Professor, University of London, England

Professor Donna Dickenson is emeritus professor of medical ethics and humanities at the University of London and research associate at the HeLEX Centre, University of Oxford. Previously she was Leverhulme Reader in Medical Ethics and Law at Imperial College School of Medicine, London. For many years she served on the Ethics Committee of the Royal College of Obstetricians and Gynaecologists, and recently presented public lectures on personalized medicine at the Royal Society of Medicine and the annual conference of the Royal College of General Practitioners. She was principal investigator of four European Commission projects in such areas as evidence-based medicine and property in human tissue. The author of 25 books and over a hundred academic articles, Professor Dickenson has published a pioneering study of personalized medicine, *Me Medicine vs. We Medicine: Reclaiming Biotechnology for the Common Good* (Columbia University Press, 2013) and a co-edited volume, *Personalised Medicine, Individual Choice and the Common Good* (Cambridge University Press, 2018). In 2006 she became the first woman to win the high-profile International Spinoza Lens Award for her contribution to public debate on ethics. Last year she presented both an invited paper on personalized medicine at the Pontifical Academy of Sciences, Rome, and a TEDx talk entitled "In Me We Trust: The Rights and Wrongs of Personalised Medicine" (available at https://www.youtube.com/watch?v=HfMIeH-j0B5A&list=PLYeC2Kl_WCI_dTGwu-yoxD1uNkXkNbvb0&index=7&t=0s).

Me Medicine vs. We Medicine: The Impact of Personalized Medicine on National and Global Health Disparities

ABSTRACT

In 2013 I published my book *Me Medicine vs. We Medicine,* in which I argued that personalized medicine (what I called "Me Medicine") risked diverting attention and resources from public health medicine (as part of the community-focused outlook that I termed "We Medicine"). In 2020 the coronavirus epidemic has cast a harsh light on the disastrous effects of cutbacks in public health and vaccine development funding. Precision medicine practitioners may not be directly to blame for those cutbacks, but national policy decisions during the past decade are certainly questionable: for example, if the $416 million earmarked back in 2011 for a four-year NIH initiative had gone into vaccine development instead, we might be in a very different position today.

My aim in this talk, however, is not to boast, "I told you so," but to show more precisely how domestic and global health policy and distributive justice are affected by precision medicine. Historically, in developed world countries, it was We Medicine—programs such as public vaccination campaigns, clean water provision, and screening for tuberculosis—that brought radically enhanced life spans and comparative freedom from contagious disease. Yet antivaccination

movements, as well as the decline in numbers of drug firms producing vaccines, have chimed there with emphasis on genomic medicine and an individualistic slant on health care. Another factor illustrating the predominance of "Me" over "We" has been the rise of pharmacogenetics, although strictly speaking that should be seen as stratified rather than fully personalized medicine.

In low- to middle-income countries, the issues about distribution and disparities are somewhat different, and, on the face of it, more conducive to We Medicine. As the Pakistani physician Farhat Moazzam argues, not only are pharmacogenetic drugs and genomic tests beyond the means of many poorer countries: the predominant social model of the extended family is hostile to the individualistic ethos of personalized medicine. Furthermore, in a patriarchal system such as she believes Pakistan's to be, decisions regarding health resources are taken by male heads of families, sometimes to the exclusion of female members' needs and interests. Finally, genomic medicine is largely concentrated in private hospitals, to which all but the wealthy lack access. High-quality primary care and prevention programs would do more to reduce health disparities than precision medicine, Moazzam asserts. One might add that where genomic medicine is beginning to develop cures of particular relevance to Third World countries, as in sickle cell disease, the vast numbers affected would make universal rollout of cures impossible.

Sandro Galea, MD, MPH, DrPH

Dean and Robert A. Knox Professor, Boston University School of Public Health

Sandro Galea, a physician, epidemiologist, and author, is dean and Robert A. Knox Professor at Boston University School of Public Health. He previously held academic and leadership positions at Columbia University, the University of Michigan, and the New York Academy of Medicine. He has published extensively in the peer-reviewed literature and is a regular contributor to a range of public media, about the social causes of health, mental health, and the consequences of trauma. Dr. Galea has been listed as one of the most widely cited scholars in the social sciences. He is chair of the board of the Association of Schools and Programs of Public Health and past president of the Society for Epidemiologic Research and of the Interdisciplinary Association for Population Health Science. He is an elected member of the National Academy of Medicine. Dr. Galea has received several lifetime achievement awards. He holds a medical degree from the University of Toronto, graduate degrees from Harvard University and Columbia University, and an honorary doctorate from the University of Glasgow.

Can Population Health Reconcile with Precision Medicine?

ABSTRACT

Can precision medicine improve population health? On the current record: not likely. There is little doubt that much discovery science can be facilitated by precision medicine approaches. But larger effects on population health remain elusive. Are population health and precision medicine then necessarily at odds? Ultimately this becomes a question of priority setting and our tolerance for varying degrees of return on our investments. This presentation will make the case for why precision medicine has not made, and is not likely to make, a difference for population health and discusses how we can think of precision medicine approaches within a population health framework.

Haidan Chen, PhD

Associate Professor, Department of Medical Ethics and Law, School of Health Humanities, Peking University, China

Dr. Haidan Chen is associate professor at the Department of Medical Ethics and Law, School of Health Humanities, Peking University (PKU), China. She gained her PhD in the philosophy of science and technology at Zhejiang University, China. Before joining PKU, she was a professor at the School of Humanities and Development Studies, China Agricultural University; a research fellow in the Science, Technology and Society Research Cluster at the Asia Research Institute, National University of Singapore (NUS); and a fellow at Tembusu College, NUS. She was a visiting postgraduate researcher at the Institute for the Study of Science, Technology and Innovation (ISSTI), the University of Edinburgh, UK (2006–2007); a visiting scholar at the Brocher Foundation, Switzerland (June–August 2011); and a Fulbright visiting scholar at the Center for Biomedical Ethics, Stanford University (2016–2017). Her research interests embrace the ethical, legal, and social implications (ELSI) of genetics and genomics, and the governance of biomedical research in China, in particular stem cell translational research, biobanks, and precision medicine.

Precision Medicine and Society: Chinese Perspective

ABSTRACT

Closely following the U.S. Precision Medicine Initiative in 2015, China launched its own version of a Precision Medicine Program in 2016 with more ambitious goals. Orientated to clinical application, the Chinese program was focused on the common diseases with high incidence and great harm, and some rare diseases with relatively high prevalence in China. In addition to building a national population-based cohort and major disease-specific cohorts of more than one million Chinese people, and to establishing a biomedical big data sharing platform, China also aimed to promote a batch of precision therapies and genetic testing products to enter the national medical insurance catalog and to make precision medicine a new growth point for economic and social development. In this presentation, I will show the ethical, regulatory, and economic issues in the development of precision medicine in China and discuss the challenges and future opportunities for precision medicine in China in the global context.

Katharina Eva Ó Cathaoir, PhD

Assistant Professor in Health Law, Faculty of Law, University of Copenhagen, Denmark

Katharina Ó Cathaoir is assistant professor in health law at Welma—Centre for Legal Studies in Welfare and Market—at the Faculty of Law, University of Copenhagen. She researches in Danish and global health law, with a focus on the implications of Big Data for the human rights of patients. She is affiliated with several interdisciplinary research projects, including Personalized Medicine in the Welfare State (MeInWe) based at the Department of Public Health, University of Copenhagen. In this project, she explores the Danish legal landscape governing use of genetic data in health care and research, focusing on patients' rights and vulnerable groups, including children and minorities.

Precision Medicine and the Danish Welfare State

ABSTRACT

The rollout of personalized medicine in Denmark—defined by the Ministry of Health as the use of advanced genetic sequencing to further accurate diagnosis and treatment—must be viewed within the context of the welfare state. The Danish tax-financed universal healthcare system facilitates the collection of vast amounts of data. Using a unique personal civil registration number, data sources—including population-based datasets and genetic data—are combined to personalize medicine. Given that public trust in state institutions is high, the Danish government has presented personalized medicine as a national endeavor that will be pursued through the publicly financed healthcare system for the benefit of patients. At the same time, the promise of a national approach masks underlying tensions.

This presentation will introduce the Danish approach to personalized medicine and explore two tensions: namely, the role private industry will play in personalized medicine, as well as the question of who will have access to genetic data. The presentation draws on an analysis of Danish law, as well as interviews with stakeholders.

In 2016, the Department of Health adopted a national strategy for personalized medicine, which describes personalized medicine as a technology that the government has chosen to invest in "for the benefit of patients." In 2018, the government agreed on legislation that establishes a legal framework for collection and storage of genetic data in a national facility—the Danish National Genome Centre. A central aim of the National Genome Centre is to store genomic data in a safe, centralized system.

Yet, the reality is that personalized medicine is unachievable as a national, healthcare endeavor alone. For example, in 2019, Novo Nordisk Foundation (a Danish commercial foundation) donated approximately 134,000 euros to the Genome Centre to facilitate the establishment of the new infrastructure. Likewise, under the legislation establishing the National Genome Centre, unless patients expressly opt out, their genetic healthcare data can be used for research. In this manner, the legislation and the National Genome Centre facilitate both treatment and research.

A wholly public approach to personalized medicine is unsustainable in a globalized world. It furthermore comes into conflict with economic realities and legal frameworks, like the GDPR, which aims to enhance the free flow of data within the EU. Similarly, framing personalized medicine as treatment ignores that, in personalized medicine, treatment and research are interconnected. Ultimately, the current approach avoids necessary conversations regarding access and equity in relation to healthcare data. The Danish approach to personalized medicine thereby marginalizes participation, which many experts view as central to the personalization of medicine.

Jorge Alberto Bernstein Iriart, PhD

Associate Professor, Instituto de Saúde Coletiva, Universidade Federal da Bahia, Brazil

Jorge Alberto Bernstein Iriart is associate professor in the Institute of Collective Health of the Federal University of Bahia in Salvador, Brazil. He holds a PhD in anthropology from Université de Montréal, Canada. His research interests center on the interface of biomedical technologies, oncological practice, patients' illness experience, and health inequities in Brazil.

Barriers, Health Inequities, and Ethical Conflicts in the Implementation of Precision Medicine Oncology in Brazil

ABSTRACT

Oncology is undergoing rapid transformation with the incorporation of precision medicine diagnostic and therapeutic technologies such as genetic testing, target drugs, and immunotherapy. The precision medicine promise to reduce the cost of medical care based on greater efficiency of drugs appropriate to the patient's genetic profile remains, however, unfulfilled. The high cost of new medicines poses a challenge for equitable access to precision oncology, especially in low- and middle-income countries marked by high social inequality. Based on ethnographic research carried out in public and private oncology clinics with a range of health professionals and patients in the cities of São Paulo, Rio de Janeiro, and Salvador, Brazil, we examine the inequities, distortions, and ethical conflicts that emerge as precision oncology is being incorporated into the Brazilian health system. We further discuss the barriers and limits for the implementation of precision oncology in this context. Brazil has the largest free and universal health system in the world whose principle is to provide integral and equal assistance to the entire Brazilian population. In practice, however, the Brazilian health system is fragmented among patients who have private health insurance, with different levels of coverage, and patients who depend only on the underfunded public subsystem. The drug approval process is complicated, and different institutions evaluate what will be available in the public and private subsystems. In this context, old and new health inequalities intertwine, and the phenomenon of judicialization emerges as a form of individual access to high-cost technologies. Our data sheds light on the conflicting interests between different social actors (pharmaceutical industry, health insurance plans, oncology clinics, public hospitals, government agencies, oncologists, and patients) and the resulting ethical conflicts and distortions. We conclude that the way in which high-cost precision medicine technologies are being incorporated into the oncological practice in Brazil is contributing to the increase of health inequalities.

Barbara Prainsack, PhD

Professor of Comparative Policy Analysis, University of Vienna, Austria

Barbara Prainsack is a professor and director at the Centre for the Study of Contemporary Solidarity (CeSCoS), Department of Political Science, University of Vienna, and a professor at the Department of Global Health & Social Medicine at King's College London. Her work explores the social, ethical, and regulatory dimensions of genetic and data-driven practices and technologies in biomedicine and forensics. Professor Prainsack is currently a member of the National Bioethics Commission in Austria and a member of the European Group on Ethics of Science and New Technologies advising the European Commission. Her latest books are *Personalized Medicine: Empowered Patients in the 21st Century?* (New York University Press, 2017), and *Solidarity in Biomedicine and Beyond* (with A. Buyx, Cambridge University Press, 2016).

The Value(s) of Precision Medicine: Societal, Political, and Ethical Aspects

ABSTRACT

Personalized medicine had, for a long time, largely focused on genetic and genomic information. In its current articulation of precision medicine it comprises a much wider range of data and information about patients and their environments. This data-centric nature of precision medicine has given rise to concerns about surveillance, overdiagnosis, and social justice (e.g., in the form of "silent rationing," as Ine van Hoyweghen and I called it). If these concerns remain unaddressed, precision medicine is likely to increase existing inequities and create new ones. At the same time, precision medicine has the potential to integrate patient-centered information, including values and other commitments of patients, as well as information on social and economic factors, more systematically into medical decision-making, and thus counteract some of the very problems that it is otherwise seen to exacerbate. For this latter vision to succeed, however, we need to change our understanding of precision medicine and how we define and measure its success. My talk will discuss these issues in a comparative perspective, addressing different configurations of visions and practices of precision, as well as different healthcare systems in the United States and Europe.

Adrian Thorogood, BCL/LLB, LLM

Academic Associate, Centre of Genomics and Policy, McGill University; Regulatory and Ethics Manager, Global Alliance for Genomics and Health

Adrian Thorogood (BA/Sc, BCL/LLB, LLM) is a lawyer and academic associate at the Centre of Genomics and Policy (CGP) at McGill University. His legal research focuses on how genomic sequencing platforms, information and networking technologies, open science practices, and patient empowerment movements are disrupting biomedical research and health care. He is also the regulatory and ethics manager of the Global Alliance for Genomics and Health, a public-private consortium that develops standards to enable responsible genomic data exchange. In this position, he leads the development of international policy frameworks addressing consent, privacy and security, and coordinated research oversight. Mr. Thorogood completed his LLM at the University of Toronto. His thesis proposed strategies to overcome incompatibilities between legal systems that hinder international health research. He holds a joint common law/civil law degree from McGill University. While at law school, he was editor-in-chief of the *McGill Journal of Law and Health*. Before entering law, he obtained a bachelor's degree from McGill University, with a double major in health economics and biomedical sciences, and worked as an epidemiology researcher and clinical trial coordinator.

Data Localization Rules: The Death Knell of the International Genomic Commons?

ABSTRACT

The genomic research community has a storied history of international collaboration. Numerous transborder genomic consortia have been established to support scientific progress and precision medicine. The governance of the genomic data commons has successfully adapted over time to comply with stricter and more fragmented data privacy laws and health research regulations. The emerging phenomenon of data localization, however, poses a serious threat to the genomic data commons. This includes laws that limit the flow of data across borders, and institutional policies that limit the flow of data across institutional (fire)walls. Data localization is more prominent as genomics moves into health care. The response of transborder genomic consortia to this phenomenon leads us to the following observations. First, there are both strategic and technological alternatives to data sharing that can still enable international scientific collaboration, though they come with important limitations and costs. Second, there are few true prohibitions on data sharing; rather, data localization tends to be pursued strategically as a response to legal uncertainty or onerous compliance costs. Before turning to imperfect alternatives, the genomics community should reaffirm the value of the international genomic data commons and renew its commitment to advancing science and improving health for all.

Patricia Danzon, PhD

Celia Moh Professor Emeritus, The Wharton School, University of Pennsylvania

Patricia Danzon is the Celia Moh Professor Emeritus at The Wharton School, University of Pennsylvania. Professor Danzon received a BA from Oxford University, England, and a PhD in economics from the University of Chicago. She has also held faculty positions at Duke University and the University of Chicago.

Professor Danzon is an internationally recognized expert in the fields of economics of health care, the biopharmaceutical industry, and insurance. She is a member of the Institute of Medicine and the National Academy of Social Insurance and a former research associate at the National Bureau of Economic Research. She has served as a consultant to many governmental agencies, NGOs, and private corporations in the US and internationally. Professor Danzon has served on the Board of Directors of Medarex, Inc., the Policy and Global Affairs Board of the National Academy of Sciences, and the Policy Board of the Office of Health Economics in London.

Professor Danzon has been an associate editor of the *American Economic Review,* the *Journal of Health Economics,* and the *International Journal of Health Care Finance and Economics*. She has published widely in scholarly journals on a broad range of subjects related to health care, pharmaceuticals, biotechnology, insurance, and the economics of law. She co-edited the *Handbook on the Economics of the Biopharmaceutical Industry* (2012) for Oxford University Press and the section on "The Biopharmaceutical and Medical Equipment Industries" in Elsevier's *Encyclopedia of Health Economics*, ed. Anthony J. Culyer, 2014. Selected publications include "Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues," *PharmacoEconomics,* 2018; "Affordability Challenges to Value-Based Pricing: Mass Diseases, Orphan Diseases, and Cures," *Value in Health,* 2018; "Exits from Vaccine Markets in the US: The Role of Competition vs. Regulation" (with N. Pereira), *International Journal of the Economics of Business,* 2011; "Value-Based Differential Pricing: Efficient Prices for Drugs in a Global Context," *Health Economics,* 2013; "Setting Cost-Effectiveness Thresholds as a Means to Achieve Appropriate Drug Prices in Rich and Poor Countries" (with A. Towse and A. Mulcahy), *Health Affairs,* 2011; "Drug Pricing and Value in Oncology" (with E. Taylor), *The Oncologist,* 2010; "Productivity in Pharmaceutical-Biotechnology R&D: The Role of Experience and Alliances" (with S. Nicholson and N. Pereira), *Journal of Health Economics,* 2005; and "Biotech-Pharma Alliances as a Signal of Asset and Firm Quality" (with S. Nicholson and J. McCulloch), *Journal of Business,* 2005.

Precision Medicine: Economic Issues

ABSTRACT

Although precision medicines face many of the issues common to R&D for other medicines, certain features are distinct to precision medicines, including pricing, cost of R&D, the potential for "cure" vs. maintenance treatment and hence return on investment (ROI), and risk. This talk will review these issues, focusing on the US but including reference to other countries.