Unintended Consequences of Healthcare & Life Science Legislation

A Global Symposium for Healthcare & Life Science Experts

Wednesday, October 15, 2014 8:00AM - 3:45PM EST 975 F Street, N.W. Washington, D.C. 20004







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Unintended Consequences of Healthcare & Life Science Legislation Symposium

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Center for Healthcare Innovation

CHI is a 501(c)(3), non-profit research center committed to excellence and innovation in the global life sciences industries, primarily the biotech, medical device, and pharmaceutical sectors. We aim to be the world's #1 source of rigorous, objective thought-leadership and innovative solutions for the international life science ecosystem.



Women In Healthcare & Life Sciences

WIHLS is an initiative to mentor and facilitate the professional development and advancement of women in healthcare and the life sciences worldwide. Through dedicated mentor-mentee relationships among women of all ages, we empower women to advance their careers, maximize their full potential, and realize their ability to affect change.



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Unintended Consequences of Healthcare & Life Science Legislation Symposium



What are the **unforeseen outcomes** of

a rapidly-changing healthcare landscape?

Unintended consequences are the unanticipated and unforeseen outcomes from government action that are not the outcomes intended by the executive and legislative branches. There are three basic categories: (i) a positive, unexpected benefit, (ii) a negative, unexpected detriment, and (iii) a perverse effect substantially contrary to the original purpose of the law or regulation. Examples in healthcare and life sciences include the *Orphan Drug Act of 1983* and the emergence of mini-med healthcare plans (total coverage capped at very low amounts). There are likely to be a wide array of unintended consequences resulting from the new *Patient Protection and Affordable Care Act* in the U.S., as well as various healthcare legislation around the world. The Unintended Consequences of Healthcare & Life Science Legislation Symposium is a non-partisan forum for healthcare and life science leaders from around the globe to discuss these unintended consequences of healthcare legislation in the U.S. around the world.

Dear Symposium Attendees,

On behalf of the Center for Healthcare Innovation (CHI), we welcome you to the 2nd annual *Unintended Consequences of Healthcare & Life Science Legislation Symposium*. It is a privilege to welcome back those who participated in last year's symposium, as well as to greet newcomers to our collaborative discussion.

Our goal for today is to provide an intimate, non-partisan, and collaborative setting for leading life science and healthcare executives, NGOs, government personnel, thought-leaders, scientists, entrepreneurs, investors, students, professors, and innovators to discuss healthcare legislation and a rapidly-changing healthcare environment. The event will feature panel discussions and distinguished speakers comprised of leading healthcare and life science experts and key opinion leaders. We hope today's symposium provides a collaborative setting to discuss the challenges and opportunities surrounding the unintended consequences of healthcare and life sciences legislation.

We would like to thank all of today's supporters, sponsors, host, copromotion partners, and distinguished moderators and panelists. Finally, we would like to thank you all for joining today's discussion. We wish you an informative and productive afternoon, and hope you enjoy today's discussion surrounding healthcare and life sciences legislation.

Kindest Regards, Symposium Planning Committee Center for Healthcare Innovation

Unintended Consequences of Healthcare & Life Science Legislation Symposium

Agenda

8:00 - 9:00	Registration & Networking
9:00 - 9:15	Opening Remarks
9:15 - 9:45	Distinguished Welcoming Address
10:00 - 11:00	Industry Perspectives Panel
11:30 - 12:30	Governmental/NGO Perspectives Panel
12:30 - 1:15	Lunch
1:15 - 2:00	Distinguished Keynote Address
2:30 - 3:30	Is Innovation at Risk? Panel Discussion
3:30 - 3:45	Concluding Remarks

Distinguished Welcoming Address: Elizabeth Flury, Chief Strategy Officer of the Children's National Health System, will set the tone for the symposium. Her position requires her to be proactive regarding healthcare reform. Ms. Flury will describe how organizations can calmly face the shifting tides of change brought about by healthcare and life science legislation.

Industry Perspectives Panel: The Affordable Care Act and other healthcare and life sciences legislation will likely have both positive and negative unintended consequences for these industries. This panel, comprised of some of the country's leading healthcare and life science executives and thought-leaders, will analyze and discuss industry reactions to healthcare and life science legislation.

Governmental/NGO Perspectives Panel: We often contemplate how the industry must react to legislation, but we do not always consider why these reforms are constructed and the guidelines that must be followed when responding to the uncertainty of the healthcare landscape. This panel, comprised of leading professionals and thought-leaders in the government and NGO sectors, will consider regulation and reform obstacles and successes.

Distinguished Keynote Address: As Director of the District of Columbia Department of Health, Dr. Joxel Garcia has firsthand experience untangling the unforeseen consequences that policy and regulation have on the healthcare the and life sciences. Dr. Garcia's broad experience and previous roles as Assistant Secretary for Health (ASH) within the U.S. Department of Health and Human Services, Four-star Admiral in the U.S. Public Health Service, U.S. Representative to the Executive Board of the World Health Organization, Founding Partner in Faunus Global and Aegis Health Security, and President of the Ponce School of Medicine & Health Sciences, give him a robust understanding of the opportunities and challenges of healthcare and life science legislation.

Is Innovation at Risk? Panel: Recent healthcare and life science legislation, including the Affordable Care Act, focuses on reducing healthcare costs and expanding coverage to all. However, legislation often has the unintended consequences of stifling innovation. This panel explores the broader intersection of healthcare and life science legislation with innovation in these industries and offers potential solutions and best practices for encouraging innovation.



Registration & Networking 8:00-9:00

Opening Remarks 9:00-9:15

• Mr. Joff Masukawa, Vice President and Global Head, Government Relations and Public Affairs, Shire

Distinguished Welcoming Address 9:15-9:45

• Ms. Elizabeth Flury, Executive Vice President and Chief Strategy Officer, Children's National Health System

Industry Perspectives Panel Discussion 10:00-11:00

- Ms. Dolly Judge, Vice President, Government Relations, Quest Diagnostics (Moderator)
- Dr. Lisa Egbuonu-Davis, Co-Founder & Director, ROI Squared
- Dr. Thomas Felix, Director, R&D Policy, Global Regulatory Affairs and Safety, Amgen
- Dr. Carol Nacy, Chief Executive Officer, Sequella
- Dr. Andrew Robertson, Director, Global Regulatory Policy, Merck; Visiting Scholar, Center for Emerging and Neglected Diseases, UC Berkeley
- Ms. Nicole Tapay, Director, Global Public Policy, Eli Lilly and Company
- Ms. Sheryl Tatar Dacso, Partner, Seyfarth Shaw
- Dr. Gillian Woollett, Senior Vice President, Avalere Health

Networking Break 11:00-11:30

Governmental/NGO Perspectives Panel Discussion 11:30-12:30

- Ms. Lauren Shweder Biel, Executive Director, DC Greens (Moderator)
- Ms. Erica Ahmed, Senior Health Communication Specialist, Leed Management Consulting, Director of Public Education, Mental Health America (former)
- Dr. Stephen Groft, Director, Office of Rare Diseases Reserach, National Institutes of Health
- Dr. Lynn Johnson Langer, Director, Enterprise & Regulatory Science Programs, Center for Biotechnology Education, Johns Hopkins University
- Mr. Peter Pappas, Principal, Innovation Strategies; Chief of Staff, United States Patent and Trademark Office, U.S. Department of Commerce (former)
- Dr. Gautam Prakash, Intellectual Property Advisor, National Heart, Lung, and Blood Institute (NIH); Patent Examiner, United States Patent and Trademark Office
- Mr. Dick Salvatierra, President, Americas Health Foundation



Lunch 12:30-1:15

Distinguished Keynote Address 1:15-2:00

• Dr. Joxel Garcia, Director, District of Columbia Department of Health

Networking Break 2:00-2:30

Is Innovation at Risk Panel Discussion 2:30-3:30

- Dr. Jeffrey Hausfeld, Founder & Chairman, Society of Physician Entrepreneurs (Moderator)
- Ms. Debra Bowes, President Emeritus/National Board Member, Women In Bio; Founder & President, Chevy Chase BioPartners
- Dr. Edward Buckley, Senior Director, US Government Relations and Public Policy, Shire
- Dr. Elizabeth Cobbs, Executive Director, HTA Strategy, Merck
- Dr. Jayne Morgan, Chief Medical Officer, The American Chemistry Council (former); Owner and Principal Consultant, Forty Million Beats
- Mr. Siva Narayanan, Senior Vice President, Ipsos
- Ms. Teresa Stanek Rea, Partner, Crowell & Moring; Deputy Undersecretary of Commerce for Intellectual Property and Deputy Director; U.S. Patent and Trademark Office (former)
- Ms. Crystal Vanuch, Head of Government Affairs and Policy, Avanir Pharmaceuticals

Closing Remarks 3:30-3:45

• Mr. Joff Masukawa, Vice President and Global Head, Government Relations and Public Affairs, Shire

Distinguished Welcoming Address

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Distinguished Welcoming Address



Ms. Elizabeth Flury
Ms. Elizabeth Flury, Executive Vice
President and Chief Strategy Officer
Children's National Health System

Elizabeth Flury, MA, is Executive Vice President and Chief Strategy Officer of Children's National Health System. She joined Children's National in 2012 as the organization's first Chief Strategy Officer. She leads the formulation and execution of new, innovative strategy at Children's National designed to ensure the organization's preparedness for healthcare reform.

Ms. Flury came to Children's National from the Johns Hopkins Health System, where she served as the Senior Director, Health Care Transformation and Strategic Planning, where she played a significant leadership role in the organization's preparations for healthcare reform. Before joining Johns Hopkins, Ms. Flury came from KPMG, where she provided national leadership to KPMG's Health Care Strategy and Governance Practice. Ms Flury has also owned and operated her own consulting firm.

Ms. Flury earned her B.S. in Business Administration from Elizabethtown College in PA, and her M.A. in Organizational Psychology from Immaculata University, also in PA.

Distinguished Keynote Address

Distinguished Keynote Address



Dr. Joxel Garcia
Director
District of Columbia
Department of Health

Dr. Joxel Garcia, MD, MBA, currently serves as the Director for the District of Columbia Department of Health (DOH). Under his leadership, the department has embarked on several innovative public health initiatives to improve and protect the health of residents, visitors, and those doing business in the District of Columbia. His health priorities include ensuring the District of Columbia receives national public health accreditation. He has also spearheaded the development of an infant mortality reduction program in collaboration with several private and public sector community partners and funders. Dr. Garcia also leads the charge in reducing/ eliminating cervical cancer and other health disparities. His priorities also include creating International Health Centers of Excellence, to establish the District of Columbia as the premiere destination for research, training, and medical tourism by the year 2015.

Dr. Garcia is committed to public health efforts to serve District of Columbia residents. His passion for health equality and identifying the social determinants of health in order to mitigate disparities is evident in the department's policy, programs, and initiatives. Prior to his appointment to the Department of Health, Dr. Garcia served as the 13th Assistant Secretary for Health (ASH) within the U.S. Department of Health and Human Services. As the Assistant Secretary for Health, he was the primary advisor to the Secretary of Health on matters involving the nation's public health system and health science. He also oversaw the U.S. Public Health Service and its Commissioned Corps and served with the rank of Admiral. In this position, Dr. Garcia was the highest ranking public health officer in the U.S. He also served as the U.S. Representative to the Executive Board of the World Health Organization.

Dr. Garcia's experience in public health encompasses health care systems, bioterrorism, public health preparedness and disaster mitigation, health policy, and global health affairs. Dr. Garcia served as the Commissioner of Public Health for the state of Connecticut and served as Deputy Director of the Pan American Health Organization (PAHO)/Regional Office Western Hemisphere for the World Health Organization. Most recently, he served as the President of the Ponce School of Medicine & Health Sciences, Ponce, and Puerto Rico.

A native of Puerto Rico, Dr. Garcia currently resides in Washington, D.C.

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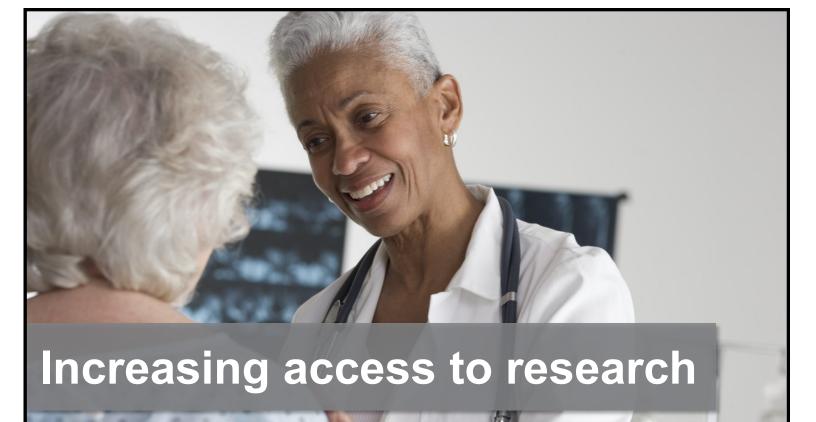
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FOR MORE INFORMATION CONTACT:

Karen E. Barnes, RN, MSN, Director, Clinical Research Exchange (312) 906-6135 or kbarnes@mchc.com

Joel Villegas, Project Coordinator, Clinical Research Exchange (312) 906-6154 or jvillega@mchc.com

About the Clinical Research Exchange (CRE)

CRE is a collaboration between the Metropolitan Chicago Healthcare Council (MCHC) and the Center for Healthcare Innovation (CHI). CRE is a clinical research alliance that streamlines the research process, enabling sites to enroll more patients more quickly.

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The Society of Physician Entrepreneurs is a global biomedical and healthcare innovation network. Founded by three physicians in early 2011, SoPE is an international nonprofit biomedical and health innovation network helping members get their ideas to patients. Membership is open to both medical professionals and other stakeholders in healthcare. SoPE is working to put healthcare innovations on the fast track----The vision, mission, and activities of the Society are ultimately about the benefit to the general public of healthcare improvements; better treatment, greater and faster access, and lower costs. To learn more about SoPE please visit our website at www.sopenet.org





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