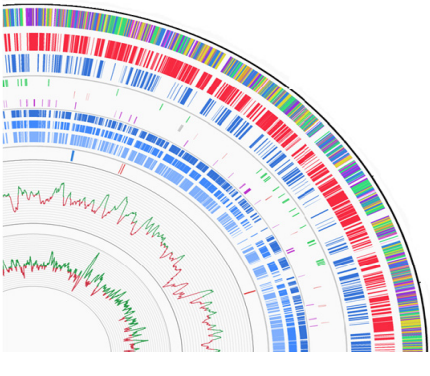
Biosimilar Insulin for the Benefit of Patients with Diabetes: Scientific, Regulatory, and Clinical Considerations

May 29, 2019

Hosted by:

Program On Regulation, Therapeutics, And Law (PORTAL) of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital/ Harvard Medical School

Harvard-MIT Center for Regulatory Science



PROGRAM ON REGULATION, THERAPEUTICS, AND LAW

PORTAL and its parent organization, the Division of Pharmacoepidemiology and Pharmacoeconomics of Harvard Medical School and Brigham & Women's Hospital, bring together concerned researchers, analysts, and trainees from the fields of medicine, law, epidemiology, and health policy to critically evaluate emerging issues on the regulation, use, and reimbursement of therapeutics (prescription drugs and medical devices). We are interested in how laws and regulations influence the development, utilization, and affordability of therapeutics, as well as the ethical questions that current and proposed policies raise for patients, physicians, policymakers, and payors.

Particular areas of focus include drug and device regulation, intellectual property, cost-effectiveness, and comparative effectiveness. These topics are addressed through a variety of descriptive, qualitative, and quantitative methodologies. Topics are often suggested by emerging policy developments that are being considered or implemented at the federal or state level.

We seek to clarify which policies, practices, and laws best promote the effective, safe, affordable, and equitable use of therapeutics. We aim for our work to be both timely and actionable, providing rigorous data and careful empirical analysis to inform ongoing debate and policymaking in this arena. Goals of this research include its publication in major medical, legal, and health policy journals; dissemination through the lay media and international, national, regional, and local professional meetings; and interaction with key decision-makers in the public and private sectors to ensure translation into actionable health care policy. PORTAL also conducts regular meetings, seminars, and conferences to discuss ongoing research, emerging areas of interest and potential scholarship, and current issues in related fields.

HARVARD-MIT CENTER FOR REGULATORY SCIENCE

Harvard, MIT, and the FDA have partnered to create a center focused on innovative approaches for the development and evaluation of medical products. Working across academia, industry, and government institutions, the Center promotes regulatory science through research and education programs, uniting stakeholders under a common mission: promoting optimal patient health outcomes through biomedical innovation and the availability of safe and effective diagnostics and treatments.

What is Regulatory Science?

Regulatory Science develops theory and methods to improve the complex process of drug and device development from discovery through post-market evaluation. This includes all aspects of the interlinked procedures used to invent a new drug or device, test it in clinical trials, and get it into the hands of patients and physicians

WELCOME

Welcome to our expert roundtable on biosimilar insulin. Insulin was originally isolated and used in clinical care about 100 years ago, with the key scientists famously donating the intellectual property for $1 each so that "anyone would be free to prepare the extract, but no one could secure a profitable monopoly." Since then, there have been a number of important improvements to the insulin product, and currently millions of people around the world depend on various forms of insulin to manage their diabetes. However, in recent years, there have been concerns about the high costs of insulin, which have led to impediments to access and disastrous patient outcomes, and have also strained limited health care resources. In response, many have asked why insulin remains without low-priced "generic" alternatives, which are common in nearly every other class of drugs with such a long history. In this meeting, we will discuss a number of the key scientific, regulatory, and clinical issues facing the production, dissemination, and use of inexpensive insulin. We have brought together experts from academia, industry, the patient advocacy community, and government to share their perspectives. How can we work together to promote availability of low-cost insulin? What are the main hurdles and what additional research is needed?

The focus of today's meeting is on insulin, and we have asked some of you to provide framing presentations today that cover three main topic areas: clinical considerations, market considerations, and scientific/regulatory considerations. We hope these comments will inspire discussion and active participation from everyone in the room on each topic. Today, we hope to foster conversation that identifies common themes and interests. To that end, we ask that everyone respect the Chatham House Rules of non-attribution; specifically, that participants are free to use any information received, but reveal neither the identity nor the affiliation of the source of that information. We hope that this approach will encourage the greatest candor and clarity, and will lay the groundwork for future collaborations.

Thank you to everyone who has joined us today. We very much look forward to hearing what everyone has to say.

Aaron S. Kesselheim, M.D., J.D., M.P.H.
Ameet Sarpatwari, J.D., Ph.D.
Jing Luo, M.D., M.P.H.
Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine Brigham and Women's Hospital and Harvard Medical School

BIOSIMILAR INSULIN

EXPERT ROUNDTABLE

May 29, 2019
Harvard Medical School, Armenise 108

Introductory Remarks
12:00 - 12:15pm

Aaron Kesselheim
Ameet Sarpatwari
Jing Luo

Session I: Clinical Considerations

12:15 - 1:15pm — Discussion leaders

Laura Marston

Kasia Lipska, Yale University School of Medicine

Teodorina Lessidrenska, T1 International

Session II: Market Considerations

1:15 - 2:15pm — Discussion leaders

Surya Singh, Singh Health Advisors

Elizabeth Jex, Federal Trade Commission (Remote)

Session III: Scientific/Regulatory Considerations

2:30 - 3:30pm — Discussion Leaders

Cory Wohlbach, Teva Pharmaceuticals

Eva Temkin, Food and Drug Administration

Session IV: Discussion Synthesis

3:30 - 4:30pm — Brainstorming: Next Steps

PARTICIPANTS

Laura Marston, J.D.

Laura serves as in-house Assistant General Counsel for an international media company, and is an unaffiliated patient leader in the fight for lower insulin prices in the United States Laura has lived with Type 1 diabetes since 1996 (diagnosed at age 14), and her personal story struggling to afford insulin has appeared in the Washington Post, BBC Global News, Vox News' "The Impact" podcast, and the feature-film documentary, "DRUG$: The Price We Pay." Laura has written on unaffordable American insulin in the British Medical Journal and was a keynote panelist at Public Citizens' 2018 Affordable Medicines Now conference.

Cory Wohlbach, B.S., Teva Pharmaceuticals

Cory (Cory.Wohlbach@tevapharm.com) is Global Vice President, Biosimilars Regulatory Affairs at Teva Pharmaceutical Industries Ltd. In this role, Cory leads Teva's regulatory strategy for biosimilar medicines. Before leading the biosimilars regulatory affairs team, Cory spent over eight years in regulatory affairs at Teva developing and gaining approval of complex generic drug products, generic drug-device combination products, sterile injectable generic drugs and biologics/biosimilars. Prior to Teva, Cory also held regulatory affairs positions at MedImmune and Sanofi Pasteur. Cory holds a B.S. in Biology from Muhlenberg College in Pennsylvania.

Ameet Sarpatwari, J.D., Ph.D., Program On Regulation, Therapeutics, And Law

Ameet (asarpatwari@bwh.harvard.edu) is an Instructor in Medicine at Harvard Medical School and an Associate Epidemiologist at Brigham and Women's Hospital. His research focuses on the effects of laws and regulations on therapeutic development, approval, use, and related public health outcomes. He is currently examining the public health impact of risk evaluation and mitigation strategies, the comparative safety and effectiveness of authorized and non-authorized generics, and the effect of variation in state drug product selection laws on prescribing.

Jing Luo, M.D., M.P.H., Program On Regulation, Therapeutics, And Law

Jing (jluo1@bwh.harvard.edu) is an Instructor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. He graduated from Duke and the University of Illinois at Chicago College of Medicine, where he was an NIH-Fogarty International Clinical Research Scholar. He is Board Certified in Internal Medicine, and serves as an associate physician at the Jen Center for Primary Care at BWH. His research focuses on prescription drug pricing, access to medicines and generic competition.

Aaron Kesselheim, M.D., J.D., M.P.H., Program On Regulation, Therapeutics, And Law

Aaron (akesselheim@bwh.harvard.edu) is a Professor of Medicine at Harvard Medical School in the Division of Pharmacoepidemiology and Pharmacoeconomics. He is Board Certified in Internal Medicine, and serves as a primary care physician at the Jen Center for Primary Care at BWH. His research focuses on the effects of intellectual property laws and regulatory policies on pharmaceutical development, the drug approval process, and the costs, availability, and use of prescription drugs both domestically and in resource-poor settings. He is a member of the FDA Peripheral and Central Nervous System Advisory Committee.

Eva Temkin, J.D., Food and Drug Administration

Eva (eva.temkin@fda.hhs.gov) is acting director of policy, Office of Therapeutic Biologics and Biosimilars, at the FDA's Center for Drug Evaluation and Research.

Elizabeth Jex, J.D., Federal Trade Commission

Elizabeth (ejex@ftc.gov) is an attorney advisor specializing in biopharmaceutical health policy in the Federal Trade Commission's Office of Policy Planning. She is a career staff attorney with over 28 years of experience in public service.

Surya Singh, M.D., Singh Health Advisors

Surya (surya.singh@singhhealthadvisors.com) is an Adjunct Instructor of Medicine at Harvard Medical School and the principal of Singh Health Advisors. Until 2018, he was Vice President and Chief Medical Officer, Specialty Pharmacy at CVS Health, where he was responsible for the company's specialty pharmacy client strategy, analytics, clinical programs and innovation.

Kasia Lipska, M.D., M.H.S., B.S., Yale School of Medicine

Kasia (kasia.lipska@yale.edu) is an endocrinologist at the Yale School of Medicine and a Clinical Investigator at the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE). Her research program seeks to better understand the balance of benefits and harms of glucose-lowering therapy in older adults with type 2 diabetes.

Teodorina Lessidrenska, T1 Internanational

Teo (Teodorina@t1international.com) is the US Program Manager for T1 International, a non-profit advocacy group run by people with and impacted by type 1 diabetes for people with type 1 diabetes. She is a researcher and international consultant in development and sustainability, with extensive experience in development activism.

Florence Bourgeois, M.D., M.P.H., Harvard-MIT Center for Regulatory Science

Florence (florence.bourgeois@childrens.harvard.edu) is Associate Professor of Pediatrics and Assistant Professor in Emergency Medicine, Harvard Medical School. She is the co-director of the Harvard-MIT Center for Regulatory Science, the Director of the Pediatric Therapeutics and Regulatory Science Initiative at Boston Children's Hospital, and served as an Expert Visitor at the European Medicines Agency, where she led a project analyzing the implementation of the EU's Pediatric Regulation to assess approaches to increase pediatric drug research and product labeling.

Special thanks

Monica Ruse, Ph.D., Harvard-MIT Center for Regulatory Science

Helen Yang, Harvard-MIT Center for Regulatory Science

Frazer Tessema, Program On Regulation, Therapeutics, And Law

Emily Jung, Program On Regulation, Therapeutics, And Law

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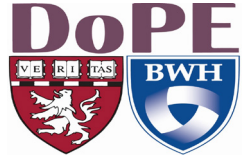
Program On Regulation Therapeutics And Law



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