KING & SPALDING

Beverly H. Lorell, M.D.

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Dr. Beverly Lorell is the Senior Medical and Policy Advisor with the firm's FDA and Life Sciences Practice in Washington, D.C. Dr. Lorell specializes in the areas of clinical trial design of studies for drugs, devices and biologics; review of pre-market submissions; recalls; and assessment of matters involving a risk to health. She also specializes in the area of physician and industry relations and the development of independent scientific panels to advise health industries.

Dr. Lorell, who was previously Professor of Medicine at Harvard University, has over twenty-five years of experience as a practicing interventional cardiologist and heart failure specialist. She is an internationally recognized clinical and basic science investigator with extensive experience in multi-center clinical trials and preclinical proof-of-concept translational science. Prior to joining King & Spalding, Dr. Lorell served as Vice President and global Chief Medical and Technology Officer at Guidant Corporation. There her responsibilities included evaluating emerging technologies and attendant regulatory challenges, determining product development priorities, and influencing clinical research strategies. She participated in the firm's board for business development.

During her career at Harvard Medical School, she served the federal government in multiple roles including:

- Food and Drug Administration's Cardiovascular and Renal Drugs Advisory Committee. Notable issues included: Irbesartan (preservation of renal function in type 2 diabetes mellitus), Pravastatin/aspirin combination (can combination be justified based on meta-analysis in absence of specific trial data supporting the combination), Losartan (nephropathy in type 2 diabetes), Candesartan (blood pressure reduction in comparison with Losartan), Omapatrilat (balancing benefit of new antihypertensive vs risk of angioedema), Ranolazine - an antianginal, Alfuzosin- erectile dysfunction, and Verdenafil - prostatic hypertrophy (balancing drug benefits vs. risks of QT interval prolongation), Ximelagatran (balancing benefits of new antithrombotic vs. risks of hepatotoxicity),
- Federally funded investigator of the National Institutes of Health,
- National task force and special emphasis panels of the National Institutes of Health, and
- The Cardiovascular Study Section of the National Heart, Lung, and Blood Institute of the National Institutes of Health.

Dr. Lorell has served in national leadership positions in professional societies. She was an Established Investigator of the American Heart Association (AHA). Additional honors include election as Fellow of the American College of Cardiology (FACC) and the American Heart Association (FAHA) and founding member of the Heart Failure Society of America. She served on the Executive Committees of both the Council on Clinical Cardiology and the Council on Basic Science of the AHA. Recent national leadership roles included the national Executive Committee of the Task Force on Clinical Competence of the ACC, AHA and American College of Physicians, a body which determines national standards for medical competency for novel cardiovascular technologies. She was also a member of the Consensus Conference Group on Professionalism and Ethics of the ACC and AHA. She continues to be an active invited lecturer at national professional meetings, as well as Harvard Law School and Harvard Medical School.

She now represents King & Spalding as a member of the Executive Committee of the New England Healthcare Institute, a nonprofit health policy organization, and as a member of the Steering Committee of the Clinical Trials Transformation Initiative, a public-private initiative between FDA, academic centers, and industry.

Dr. Lorell is a graduate of Stanford University, and she received her M.D. degree and her Residency in Internal Medicine from Stanford University Medical School. She received her advanced training as a Fellow in Cardiovascular Medicine at Harvard University. She is a Diplomate of the American Board of Internal Medicine, the Subspecialty Board of Cardiovascular Disease, and the Subspecialty Board of Interventional Cardiology. She is admitted to practice medicine in the states of California and Massachusetts. She is the author of over 160 medical science publications, 26 chapters and 2 books, including 8 recent publications in the area of health policy. Edward M. Basile, Partner at King & Spalding, and Dr. Lorell are authors of the recent publication, *The Food and Drug Administration's Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency's Regulatory Framework?,* 61 FOOD AND DRUG LAW JOURNAL 251-272 (2006).

Recent Publications

- Co-author, *The Food and Drug Administration's Regulation of Risk Disclosure for Implantable Cardioverter Defibrillators: Has Technology Outpaced the Agency's Regulatory Framework?,* 61 FOOD AND DRUG LAW JOURNAL 251-272 (2006)

Memberships

- Established Investigator of the American Heart Association (AHA)
- Fellow of the American College of Cardiology (FACC)
- Fellow of the American Heart Association (FAHA)
- Founding Member of the Heart Failure Society of America
- Council on Clinical Cardiology, Executive Committee
- Council on Basic Science of the AHA, Executive Committee
- Executive Committee of the Task Force on Clinical Competence of the ACC, AHA and American College of Physicians
- Consensus Conference Group on Professionalism and Ethics of the ACC and AHA
- American Board of Internal Medicine, Diplomate
- Subspecialty Board of Cardiovascular Disease
- Subspecialty Board of Interventional Cardiology

Credentials

EDUCATION

B.A., Stanford University
M.D., Stanford University

Insights

CLIENT ALERT

December 11, 2020
Department of Justice Vows Vigorous Enforcement of Clinical Trial Fraud

November 19, 2020
Heightened Focus on Foreign Influence in Academia

August 17, 2020
Federal Government Takes Steps Toward Enforcement of ClinicalTrials.gov Requirements

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Events

WEBINAR

March 16, 2021
The New Intensified Scrutiny and Enforcement of FDA-Regulated Clinical Trials

November 10, 2020
13th Annual King & Spalding Medical Device Summit

April 3, 2020
Clinical Trials During the COVID-19 Pandemic and Recent Court Decision on ClinicalTrials.gov

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