

EMERGING ISSUES IN FOOD & DRUG LAW

*A National Conference
for Lawyers, Policy-Makers,
and Corporate Leaders*

MONDAY, NOVEMBER 16, 2009

Keynote speakers:

Dr. Andrew C. von Eschenbach

*Former Commissioner of Food and Drugs,
U.S. Food and Drug Administration*

Jeffrey M. Senger, Esq.

Deputy Chief Counsel, U.S. Food and Drug Administration



*Hosted by the University of Maryland School of Law,
Whiteford, Taylor & Preston, LLC, Greenleaf Health, LLC and the
University of Maryland School of Pharmacy Center on Drugs & Public Policy*

IT IS A CRITICAL TIME in the food and drug industry and within the U.S. Food and Drug Administration (FDA or the Agency). New regulators, policy-makers, and industry leaders are engaged in intense policy debates that will shape the face of food and drug law for decades to come. Join regulators, industry leaders, and legal experts in a day-long conference dedicated to emerging issues in food and drug law. Attend this year's conference, meet FDA regulators and experts in the field, and participate in a critical dialogue on these hot-button issues:

A Regulatory Pathway for Follow-On Biologics

The U.S. Congress is considering creating an abbreviated approval pathway for follow-on biologics (also referred to as biosimilars or follow-on protein products). There is substantial debate among regulators and policymakers over scientific and legal issues involved in creating this approval pathway. This panel will discuss the scope of FDA's use of the 505(b)(2) approval process, the pending follow-on legislation, immunogenicity, exclusivity periods, clinical trials and other essential issues in this debate.

Preemption and the Impact of *Riegel v. Medtronic* and *Wyeth v. Levine* On Drug and Device Labeling

These two Supreme Court cases, one involving a medical device and the other a drug, have altered the landscape for the preemptive effect of medical device and drug labeling. This panel will discuss these seminal Supreme Court decisions and their impact on the preemptive effect of product labeling on state tort claims. Panelists will discuss the policy and legal implications of these decisions from a regulatory and patient perspective.

Navigating FDAAA: The Challenges of Risk Evaluation & Mitigation Strategies (REMS)

REMS were a principal feature of the Food and Drug Administration Amendments Act (FDAAA) of 2007. REMS were intended to usher in a new era of drug safety and post-market drug surveillance. However, FDA's implementation of REMS and the industry's consternation about these provisions of FDAAA have caused substantial debate. This panel will discuss the regulatory progress in implementing REMS and the principal hurdles facing the industry in complying with the law. This panel will also address related provisions of FDAAA meant to enhance the effect of REMS.

The Future of Generic Drugs: Patents, Exclusivity, and Litigation.

Generic drugs provide a bioequivalent substitute for more expensive innovator drug products. However, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) has been criticized for its purported weaknesses in facilitating the timely entry of generic drugs onto the market. This panel will discuss the effectiveness of Hatch-Waxman, including exclusivity, anti-trust, and patent issues.

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THE UNIVERSITY OF MARYLAND

SCHOOL OF LAW

500 W. BALTIMORE STREET,
BALTIMORE, MD 21201-1786

Cost *\$150*
(includes all conference materials,
breakfast, lunch and admission to the
post-conference reception)

Registration *www.law.umaryland.edu/foodanddrug*

Questions *410.706.2088*

Hosts *University of Maryland School of Law*
Whiteford, Taylor & Preston, LLP
Greenleaf Health, LLC
University of Maryland School of Pharmacy
Center on Drugs & Public Policy

8:30 am

Registration & Continental Breakfast

9:15 am

Conference Opening Remarks

Diane E. Hoffmann, J.D., M.S.

*Associate Dean for Academic Programs,
Director, Law and Health Care Program,
University of Maryland School of Law*

Jeffrey M. Senger, Esq.

Deputy Chief Counsel, U.S. Food and Drug Administration

10:00 am

Panel: Preemption and the Impact of *Riegel v. Medtronic* and *Wyeth v. Levine* on Drug and Device Labeling

11:15 am

Panel: A Regulatory Pathway for Follow-on Biologics

12:30 pm

Lunch with Keynote Speaker

Dr. Andrew von Eschenbach

*Former Commissioner of Food and Drugs,
U.S. Food and Drug Administration*

Recognition of the 25th Anniversary of University of Maryland's Nationally-Ranked Law & Health Care Program

2:00 pm

Panel: Navigating FDAAA: The Challenges of Risk Evaluation & Mitigation Strategies (REMS)

3:30 pm

Panel: The Future of Generic Drugs: Patents, Exclusivity, and Litigation

5:00 pm

Networking Reception for Speakers & Attendees

CONFIRMED SPEAKERS

Dr. Andrew C. von Eschenbach

Former Commissioner of Food and Drugs
Senior Advisor, Greenleaf Health LLC

Jeffrey M. Senger, Esq.

Deputy Chief Counsel, U.S. Food and Drug Administration

Sheldon Bradshaw, Esq.

Partner, Hunton & Williams (former FDA Chief Counsel)

Gerald F. Masoudi, Esq.

Partner, Covington & Burling LLC (former FDA Chief Counsel)

Elizabeth H. Dickinson, Esq.

*Associate Chief Counsel for Drugs, Office of the Chief Counsel,
U.S. Food and Drug Administration*

Brian Wolfman, Esq.

*Institute for Public Representation,
Georgetown University Law Center (formerly of Public Citizen &
Counsel for respondent in *Wyeth v. Levine*)*

Jennifer L. Bragg, Esq.

Partner, Skadden, Arps, Slate, Meagher & Flom

Robert A. Dormer, Esq.

Partner, Hyman, Phelps & McNamara, P.C.

§ **Diane E. Hoffmann, J.D., M.S.**

*Associate Dean & Director, Law & Healthcare Program,
University of Maryland School of Law*

Kay Holcombe

Senior Health Policy Advisor, Genzyme Corporation

§ **Jeremiah J. Kelly, Esq., M.P.P.**

Associate, Whiteford, Taylor & Preston

Bruce Lehman, Esq.

*Senior Counsel, Whiteford, Taylor & Preston
(former Commissioner of Patents & Trademarks)*

§ **Francis B. Palumbo, Ph.D., J.D.**

*Executive Director, University of Maryland School of Pharmacy Center
on Drugs and Public Policy*

Sheila Weiss Smith, Ph.D.

*Director, the Center for Drug Safety,
University of Maryland School of Pharmacy*

Lawrence Sung, J.D., Ph.D.

*Director, Intellectual Property Law Program,
University of Maryland School of Law*

The List of Confirmed Speakers is updated regularly. Please visit www.law.umaryland.edu/foodanddrug for the most recent list. Papers from this conference will be published in the upcoming Spring 2010 edition of the School of Law's *Journal of Health Care Law & Policy*.

§ Conference Executive Committee Member