Hamline Law Review
2009 Symposium

April 3, 2009
Klas Center, Hamline University

The Food, Drug, and Cosmetic Act –
Searching for the Crossroads of Safety and Innovation

In a 2008 U.S. Supreme Court decision, *Riegel v. Medtronic*, the opportunity to bring state tort claims against medical device manufacturers that make FDA-approved devices diminished significantly due to a preemption clause in the Medical Device Amendments to the FDCA. This ruling answered questions presented by a 1996 decision in which the Supreme Court faced, but choose to disallow preemption of, similar claims against a device that had been grandfathered into the market under a provision of the Amendments. After the most recent ruling, courts around the country have seen a flood of court filings from device manufacturers seeking dismissals of state personal injury suits against their products. The decision additionally spurred threats from Congress to introduce legislation to overturn the decision – which it has since done with the presentation of the *Medical Device Safety Act of 2008*. The Supreme Court heard arguments this fall in *Wyeth v. Levine*, a case involving federal preemption of state tort claims against drug manufacturers and their FDA-approved labeling. Because the FDCA's drug provisions do not explicitly preempt state law claims, but do require FDA pre-market approval of all new drugs, one must wonder if the Court will continue on this path of state tort law constriction.

Symposium Sponsored by:

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Schedule

8:00-8:30	Registration
8:30-8:50	Introduction Dean Don Lewis, Hamline University School of Law
8:55-9:40	***Prescription Drug and Medical Device Preemption: Where We Are and Where We May Be Headed*** James Beck, Dechert LLP
9:45-10:30	***Congressional Oversight of Supreme Court Preemption Decisions*** Richard Samp, Washington Legal Foundation
10:35-11:20	***Preemption in Pharmaceutical Litigation After Levine*** Robert Weiner, Arnold & Porter LLP
11:25-12:10	***Agency Accountability: Federal Preemption's Future*** Catherine Sharkey, Professor, NYU School of Law
12:10-1:10	**Lunch**
1:10-1:55	***Preemption of Product Liability Claims Against Drug and Medical Device Manufacturers*** David Prince, Professor, William Mitchell College of Law
2:00-2:45	***FDA Preemption, Wyeth, Congress, and a Crystal Ball*** David Vladeck, Professor, Georgetown University Law Center
2:50-3:35	***Name Brand Exposure for Generic Drug Use: Prescription for Liability*** Bridget Ahmann, Faegre & Benson LLP
3:40-4:30	**Panel – *Moderated by*** Professor Lucinda Jesson, Director, Health Law Institute Hamline University School of Law

Questions? Contact Jessica Taralson, Symposium Editor
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Want to RSVP? Contact Deb Lange at dlange@hamline.edu

James Beck, Dechert LLP

James M. Beck is counsel in the mass torts and product liability group. Mr. Beck is primarily engaged in the defense and appellate practice involving complex personal injury and product liability matters. Mr. Beck has overseen the development of legal defenses, maintenance of master briefs, and the prosecution of summary judgment motions in mass tort litigation, including Seroquel, Diet Drugs, Baycol, and orthopedic bone screws. In the Orthopedic Bone Screw litigation, the resulted was successful summary judgments in over 170 cases, all of which were successfully defended on appeal.

Professional Activities: Mr. Beck has been an elected member of the American Law Institute since May, 2006. He is active in the Members Consultative Groups concerning Principles of Aggregate Litigation and Restatement of the Law Third Economic Torts and Related Wrongs. Mr. Beck is a member of the Product Liability Advisory Committee (PLAC) and has sat on PLAC's case selection committee since 1997. He has written over 50 amicus curiae briefs on product liability issues for PLAC. Mr. Beck has also prepared amicus briefs for the American Bar Association, the American Civil Liberties Union, the United States Chamber of Commerce, the Business Roundtable, the American Medical Association and several of its state affiliates, the Pennsylvania Defense Research Institute, and the Washington Legal Foundation. Mr. Beck is also a member of the Defense Research Institute and of the American, Pennsylvania, and Philadelphia Bar Associations.

Unprofessional Activities: Mr. Beck is co-owner and a regular contributor to the Drug and Device Law Blog, http://druganddevicelaw.blogspot.com/, the most widely read product liability blog on the Internet.

Court Admissions: Admitted to practice in federal and state courts in Pennsylvania, in the Supreme Court of the United States, and in various federal and state court pro hac vice.

Education: Princeton University, B.A., cum laude, 1978; The University of Pennsylvania Law School, J.D., 1982.

Richard Samp, Washington Legal Foundation

Richard Samp is Chief Counsel of the Washington Legal Foundation, a nonprofit public interest law firm located in Washington, D.C. WLF litigates in support of individual rights and the free-enterprise system and against excessive government regulation. Mr. Samp served as lead counsel in *WLF v. Friedman*, a federal court decision striking down – on First Amendment grounds – FDA restrictions on the dissemination of peer-reviewed medical journal articles that contain information about off-label uses of approved drugs. Mr. Samp also served as lead counsel in *Abigail Alliance v. von Eschenbach*, in which terminally ill patients asserted a constitutional right of access to developmental drugs if they have no other available treatment options. Mr. Samp has regularly litigated in federal court in support of broad federal preemption of state tort actions against the manufacturers of FDA-approved products. *See, e.g., Wyeth v. Levine, Warner-Lambert v. Kemp, Riegel v. Medtronic, Buckman v. Plaintiffs' Legal Committee*, and *Medtronic v. Lohr*.

Mr. Samp is a 1974 graduate of Harvard College and received his law degree from the University of Michigan in 1980. Before joining WLF in 1989, Mr. Samp was a litigator at the Washington, DC law firm of Shaw Pittman.

Catherine Sharkey, Professor
New York University School of Law

Catherine Sharkey is Professor of Law at New York University School of Law. She has published numerous scholarly articles in her areas of expertise: punitive damages, federal preemption of state products liability law, class actions, and empirical legal studies. Her articles on preemption have been cited by the U.S. Supreme Court, the Third Circuit Court of Appeals, and a federal district court in Louisiana. She is a senior editor of the *Journal of Tort Law* and an adjunct senior fellow at the Institute for Civil Justice at RAND Corporation. After graduating from Yale Law School, she served as law clerk to the Honorable Guido Calabresi of the United States Court of Appeals for the Second Circuit and to the Honorable David H. Souter of the United States Supreme Court.

Robert Weiner, Arnold & Porter LLP

Robert Weiner, former head of the litigation practice group at Arnold & Porter, LLP, is a leading national expert on pharmaceutical and medical device preemption. Among other things, he has filed amicus briefs or otherwise been involved in the three recent pharmaceutical and medical device preemption cases the Supreme Court has considered: *Riegel v. Medtronic, Inc., Kent v. Warner-Lambert Inc.* and Wyeth *v. Levine*. He has also written amicus briefs on preemption on behalf of the Product Liability Advisory Council and the Pharmaceutical Research and Manufacturers Association (PhRMA) in the U.S. Supreme Court, the Second, Third, Seventh, Eighth, and Tenth Circuits, the Pennsylvania Supreme Court, and the New Jersey Supreme Court. In addition, he has briefed, argued, and consulted on preemption issues for pharmaceutical manufacturers in matters before trial courts, regulatory agencies, and legislatures. Recently, for PhRMA, Mr. Weiner tried a First Amendment and preemption challenge to a restriction on pharmaceutical marketing in Vermont. The Court has the issue under advisement.

Mr. Weiner has lectured on or debated pharmaceutical and medical device preemption at the American Conference Institute, Practicing Law Institute, Washington Legal Foundation, Civil Justice Reform Group, Product Liability Advisory Council, American Bar Association Administrative Law Section, and the Center for Business Intelligence, has presented seminars for clients on the subject, and has appeared on national news programs discussing the issue. He has also taught as a Visiting Lecturer at the University of Virginia School of Law and as an Adjunct Professor at the Georgetown University Law Center.

Mr. Weiner is a graduate of Princeton University (*summa cum laude*) and Yale Law School. He clerked for Judge Henry J. Friendly of the U.S. Court of Appeals for the Second Circuit and for Justice Thurgood Marshall of the U.S. Supreme Court. From 1997-98, Mr. Weiner was Senior Counsel in the Office of the White House Counsel, handling the legal aspects of major public policies, including issues relating to the proper balance of decision-making authority between federal and state government. Mr. Weiner has also served as President of the District of Columbia Bar and, most recently, chaired the District of Columbia Bar Foundation, which funds legal services for the poor.

David Prince, Professor
William Mitchell College of Law

David Prince has been Professor of Law at William Mitchell College of Law since 1977. He currently lectures in products liability law and toxic tort litigation. During his tenure at William Mitchell, he also served as Vice Dean from 1999-2002. In addition to teaching, Mr. Prince serves as Counsel at Larson King in Saint Paul, Minnesota. He focuses his practice on products safety and product liability prevention, mass tort and products liability litigation, appellate advocacy and alternative dispute resolution. Mr. Prince has published articles addressing products liability claims in Minnesota in a number of law reviews and sat on numerous panels discussing administrative and regulatory issues. Mr. Prince is co-editor of a products liability law online blog and a former part-time administrative law judge.

Bridget Ahmann, Faegre & Benson LLP

Bridget Ahmann is a Partner at Faegre & Benson in Minneapolis, Minnesota. Her practice focuses on product liability and mass torts, with a particular emphasis in pharmaceutical and medical device litigation, with a significant portion concentrating on the defense of mass torts litigation on a nationwide or regional basis. Her role often involves issues related to science, such as expert development or motion practice, or legal defenses, such as class action, medical monitoring or preemption. Ms. Ahmann has worked on defense teams in a variety of class action, multidistrict and mass tort litigation involving anti-psychotic medication, antidepressants, hormone therapy, diet drugs, silicone gel breast implants, orthopedic implants, latex gloves, vaccines, blood factor concentrates, contaminated food products, asbestos and silica. Ms. Ahmann has also given various presentations on federal preemption and products liability law development.

David Vladeck, Professor
Georgetown University Law Center

David C. Vladeck is a Professor of Law at Georgetown University Law Center. He teaches courses in federal courts, government processes, civil procedure, first amendment litigation, and co-directs the Institute for Public Representation, a clinical law program at the Law Center where he handles a broad array of civil rights, civil liberties, first amendment, open government, and regulatory litigation. Prior to joining the Georgetown faculty in 2002, Professor Vladeck spent nearly 30 years with Public Citizen Litigation Group, serving as its Director from1992 to 2002. He has handled a wide range of complex litigation, primary in federal courts, including first amendment, health and safety, civil rights, class actions, preemption and open government cases. He has argued a number of First Amendment and civil rights cases before the United States Supreme Court, and more than 60 cases before the federal courts of appeal and state courts of last resort.

Professor Vladeck testifies frequently before Congress, advises Members of Congress on legal matters, and writes on administrative law, preemption, first amendment, legal ethics, and access to justice issues. He serves as a Scholar with the Center for Progressive Reform and on the boards of various non-profit organizations. He is a member of the American Law Institute and the Institute of Medicine's Committee on Strategies to Reduce Sodium Intake. He has also served on the Council of the Administrative Law and Regulatory Practice Section of the American Bar Association, as a Public Member of the Administrative Conference of the United States, and as the Chair of the Administrative Law Section of the District of Columbia Bar. Professor Vladeck received his undergraduate degree from New York University, his law degree from Columbia University School of Law, and an LL.M. degree from Georgetown University Law Center. In May 2008, *Legal Times of Washington* recognized him as one of 30 "champions of justice," and one of the 90 greatest lawyers in Washington, D.C., over the past 30 years.