

## Harold J. Decker

### SERVICE AREAS

#### Business

- Intellectual Property
  - Licensing
  - Patents
- Life Sciences

#### Litigation + Trial

- Intellectual Property Litigation

#### Governments + Nonprofits

- Intellectual Property
  - Licensing
  - Patents
- Life Sciences

### EDUCATION

- Southwestern University School of Law, J.D.
- Southwestern University School of Law, LL.D.
- Kalamazoo College, B.A.

### BAR ADMISSIONS

- California
- District of Columbia
- Michigan

### COURT ADMISSIONS

#### U.S. Supreme Court

#### U.S. Courts of Appeals

- Sixth
- Ninth
- Federal

#### District of Columbia Court of Appeals

#### U.S. District Courts

- Central California



### Of Counsel

#### Kalamazoo

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Harold J. Decker has been resolving serious problems for clients for over 34 years. He has represented clients in many forms of litigation, including commercial disputes, product liability suits, medical malpractice cases, railroad accidents and banking cases, to name just a few. Harold has also served as a court-appointed and private arbitrator. He specializes in the development and implementation of records management programs, litigation readiness plans and pro-active discovery strategies.

*"Throughout my career I have devoted myself to solving, not just identifying problems for clients. To accomplish that goal I focus on the task with imagination, energy and effort."*

Harold J. Decker

In addition to practicing law, Harold agreed to serve as the Interim President and Chief Executive Officer of The American National Red Cross shortly after the September 11, 2001, terrorist attacks. For the next year he led the Red Cross during one of the most trying times in the history of the organization and the nation. Prior to his service at the Red Cross, Harold was associate general counsel and vice president of Corporate Litigation and Product Stewardship at Pharmacia (formerly Upjohn).

Over the years, he has faced challenges that required thoughtful consideration and decisive action. He has combined experience with imagination and an incredible work ethic to successfully guide clients in diverse industries that include pharmaceuticals, biotechnology, medical devices, hotels, automobiles, communications and nonprofit organizations.

In addition to his experience trying cases, Harold has provided counsel to companies in these industries in an effort to avoid costly litigation. These services have included pre-launch audits,

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- Northern California
- Western District of Michigan
- Eastern District of Michigan

pre-litigation audits, package labeling and riskMAP reviews, records retention policy reviews, company employee lectures on “product stewardship,” and helping to shape evidence developed in parallel proceedings.

Recently Harold has devoted a substantial amount of time to creating an intellectual property group within the firm that speaks the same idiom as the inventors it serves, guides clients through regulatory issues and does so in a cost-effective manner. He also served as a spokesperson for his clients during times of crisis on CNN, CNBC, “60 Minutes,” “20/20,” “Nightline,” NPR, and the editorial boards of The New York Times, The Wall Street Journal and The Washington Post.

### EXPERIENCE

On two days notice Harold left his home and moved into a hotel 800 miles away for 18 months in a successful effort to extricate a client from a staggering list of problems that included a U.S. Senate Finance Committee investigation, a formal notice of investigation by the SEC and an investigation by a U.S. Attorney along with product liability, shareholder, derivative, employment, commercial, patent, *qui tam* and commercial litigation problems, among others.

*“I was able to bring these matters to a successful conclusion because I had the experience to know what to do and the enthusiasm and the energy to get it done.”*

He has served as counsel for AureoGen Biosciences, Inc., Biogen Idec, Inc., CAPECOD Biosystems, Inc., Cortex Pharmaceuticals, Inc., Genzyme Corporation, Mascoma Corporation, Inc., Microsoft Corporation, Perrigo, Inc., Pfizer, Inc., Synthes Inc and Vertex Pharmaceuticals Incorporated.

The products he has defended include: agronomic seeds, analgesics, antibiotics, anticoagulants, anxiolytics, biologics, chemotherapeutics, corticosteroids, cough/cold remedies, synthetic estrogen, erectile dysfunction medication, hormone replacements, hypnotics, medical devices, monoclonal antibodies, synthetic progesterone and veterinary products. He has also been responsible for the defense of purported class actions, as well as shareholder and derivative litigation.

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During his service with The Upjohn Company, he was the in-house attorney with responsibility for the defense of all the Company's litigation, including: "In re Upjohn Co. Antibiotic 'Cleocin' Prods. Liab. Litig. (MDL 343) and In re Brand Name Prescription Drug Antitrust Litigation (MDL 997)." In addition to litigation, Mr. Decker was responsible for product stewardship efforts, including:

- Review and comment on the product liability consequences of proposed language for inclusion in informed consent forms and Investigator brochures
- Preparation for FDA interaction (End of Phase II, label review, and Advisory Committee meetings)
- Review and assistance in drafting the labeling of products for use by both physicians and patients (so-called "package inserts") in countries around the world in aid of the clients ability to avoid product liability litigation, primarily in the US
- Responding to "establishment inspections" by Inspectors from the Food & Drug Administration, including initial meetings, responding to Establishment Inspection Reports, FDA Form 483 Inspectional Observations and Citizens Petitions
- Conduct of product-launch audits, including interviews of key employees (project management, clinical development, pre-clinical development, regulatory affairs, pharmacovigilance, and key documents (integrated summaries of efficacy and safety, riskMAP, labeling, MSDS sheets) to identify litigation risks and suggest alternative solutions to avoid risk
- Appearing as the clients spokesperson before: the Food & Drug Administration in the US, the Medicines Commission in Great Britain, the Institute of Medicine, staff counsel to majority and minority members of the House Energy and Commerce Committee, which has oversight responsibility for the Food & Drug Administration, among other agencies
- Assist Public Relations personnel with the creation of public statements, including press releases, company generated questions and answers, white papers, and service as the "spokesperson" for the client in the national media
- Delivery of many educational seminars to employees of clients as a means of reducing product liability risk

## Harold J. Decker

Harold has also represented clients in cost recovery actions, including insurance coverage and other contract disputes over indemnification for personal injury and property damage claims before courts, the American Arbitration Association, the London Court of International Arbitration and the International Chamber of Commerce.

As the President and Chief Executive Officer of the Red Cross, Harold was responsible for the 36,000 employees and 1.2 million volunteer members of the organization. He also exercised administrative control over the two main businesses of the organization: the collection and processing of approximately one half of the nation's blood supply and preparation for and response to over 67,000 natural and man-made disasters per year. In the performance of his duties he consulted with members of the United States government, including: the President of the United States, the Secretary of Health and Human Services, the Chief Counsel of the Food and Drug Administration, the Secretary of the Department of Homeland Security, the Director of the Federal Emergency Management Administration, the Deputy Secretary of State and numerous members of Congress.

Outside the US, Harold has worked on the resolution of disputes in Belgium, Brazil, Canada, France, Japan, Mexico, The Netherlands and The United Kingdom.

### PROFESSIONAL ACTIVITIES

- American Bar Association, Litigation Section; Products Liability Committee; Co-Chair, Biotechnology Subcommittee
- American Judicature Society
- Federal Bar Association, Western Michigan Chapter
- State Bar of Michigan, Litigation Section
- State Bar of California, Litigation Section
- District of Columbia Bar Association, Intellectual Property Section
- Kalamazoo County Bar Association
- Michigan Defense Trial Counsel, Inc.

### HONORS + AWARDS

- Kalamazoo College Distinguished Alumni Award
  - Interim CEO Hall of Fame
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## Harold J. Decker

- The W. E. Upjohn Prize
- Best Lawyers in America, Biotechnology Law, Commercial Litigation 2010-present; Litigation-Intellectual Property 2012
- Thought Leaders in the Law, Business Review West Michigan 2010

### **CIVIC, CULTURAL + SOCIAL ACTIVITIES**

- Southwestern University School of Law, Board of Visitors, 2011
- Kalamazoo College, Board of Trustees, 2010-present

### **MILITARY EXPERIENCE**

- Vietnam Service Medal, Vietnam Campaign Medal, Army Commendation Medal, Air Medal, Bronze Star Medal, Expert Combat Infantryman Badge, American Spirit Honor Medal

### **TEACHING EXPERIENCE**

- Thomas M. Cooley Law School, Adjunct Professor, 1986-98

### **PUBLICATIONS**

"New Federal e-discovery Rules: A Blessing or a Curse?" Midwest In-House, July 2006

"Practice Tips for Getting Control over Internal Records," Midwest In-House, January 2004

"Practical Suggestions for Record Retention," Legal Insight This Week (Midwest In-House), February 9, 2004

### **SPEECHES**

Annual Day of Education, (Panelist), State Bar of Michigan, May 6, 2011

Kalamazoo College 2009 Convocation, Keynote Address, Kalamazoo, Michigan, September 16, 2009

"Leadership In Difficult Times," Illinois State Medical Society Annual Meeting, Oakbrook Hills, Illinois, April 24, 2009

"Product Liability Implications for Adverse Event Reporting and Labeling," Pharmaceutical Education & Research Institute, Washington, D.C., April 1, 2008

## Harold J. Decker

"Best Practices for Identifying and Minimizing the Risks of Marketing New Products," The Center for Business Intelligence, Webinar, December 4, 2007

"Product Liability Implications of Adverse Event Reporting and Labeling," Pharmaceutical Education & Research Institute, Arlington, Virginia, November 6, 2007

"Recalls and Other Tough Calls (Crisis Management Issues)," Section of Litigation, ABA, Second Annual Biotech Institute and Regional CLE Workshop, South San Francisco, California, October 2, 2007

"Product Liability Implications for Adverse Event Reporting and Labeling," Pharmaceutical Education & Research Institute, Arlington, Virginia, March 13, 2007

"Recall and Other Tough Calls (Crisis Management Issues)," Section of Litigation, ABA, First Annual Biotech Institute and Regional CLE Workshop, Cambridge, Massachusetts, October 18, 2006

"Product Liability Litigation and the Pharmacovigilance Professional," Pharmaceutical Education Research Institute, Arlington, VA, September 26, 2006

"Board Responsibilities and Leadership in a Crisis," Volunteer Center of Greater Kalamazoo, Kalamazoo Regional Chamber of Commerce, Kalamazoo, Michigan, May 20, 2005

"The American Red Cross Post 9/11: A Case Study in Organizational Governance and Ethics," Ford Motor Business Lecture, Inaugural Executive In Residence Community Address, Kalamazoo College, Kalamazoo, Michigan, May 12, 2005

"Humanitarian Commitment by Young People in Times of International Disaster," Phillips Academy, Andover, Massachusetts, February 10, 2005

"Information Management in the Electronic Age," The West Michigan Chapter of the Association of Corporate Counsel Americas, Grand Rapids, Michigan, December 7, 2004

"When Nobody's Watching: Ethics in Action," Public Relations Society of America, West Michigan Chapter, Keynote Speaker "A Perspective on Ethics," September 28, 2004

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"Product Liability Implications for Adverse Event Reporting and Labeling," Pharmaceutical Education Research Institute, Arlington, Virginia, September 21, 2004

"Leadership in a Crisis," Leadership Kalamazoo, Chamber of Commerce, Kalamazoo, Michigan, June 8, 2004

"Information Management in the Electronic Age," The East Michigan Chapter of the Association of Corporate Counsel Americas, Dearborn, Michigan, June 2, 2004

"Applying the Principle of Alignment: Lessons on Leadership from the American Red Cross," Miller Canfield University Leadership in the Lawn Firm: Aligning the Stars, Miller, Canfield, Paddock, and Stone, P.L.C., Ann Arbor, Michigan, May 8, 2004

"Adverse Events: A Review of Regulations and Challenging Exercises in Pharmacovigilance," Pharmaceutical Education Research Institute, Arlington, Virginia, March 30, 2004

"Our Federalism: Court Problems and Potential Solutions in Multi-District Litigation, Class Action and Consolidated Mass Tort Litigation," American Bar Association, Member of Panel, 2004 Section of Litigation Environmental, Products Liability and Mass Torts Committees Joint CLE Seminar, Orlando, Florida, March 26, 2004

"Accepting the Leadership Challenge," Chamber of Commerce, Greater Las Cruces, New Mexico, October 21, 2003

"Product Liability Implications for Adverse Event Reporting and Labeling," Pharmaceutical Education & Research Institute, Arlington, Virginia, September 30, 2003

"Honoring Those Who Made a Difference," Chamber of Commerce, Greater Las Cruces, New Mexico, July 1, 2003

"The Paul E. and Phyllis Treusch Public Service Lecture," Southwestern University School of Law, Los Angeles, California, April 9, 2003

"Legal Aspects of Adverse Events: A Review of Regulations and Challenging Exercises in Pharmacovigilance," Pharmaceutical Education & Research Institute, Arlington, Virginia, October 24, 2002

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"The New Era of Board Accountability," Governing Nonprofits for Success, The Dorothy Johnson Center for Philanthropy and Nonprofit Leadership, Grand Valley State University, Grand Rapids, Michigan, September 20, 2002

"Challenges in Times of Change," Town Hall, Los Angeles, California, August 1, 2002

"Charitable Organization Response to the Events of September 11, 2001," Executive Policy Forum, Princeton, New Jersey, April 23, 2002

### SEMINARS + EVENTS

- MichBio Expo: Moderator CEO Dinner Forum
- Global Pharmacovigilance Training Course: Adverse Drug Events
- Biotech Institute and Regional CLE Workshop: Collaboration Agreements

### NEWS

- Miller Canfield Lawyer Harold Decker Elected to Kalamazoo College Board of Trustees
- Miller Canfield Attorney Harold Decker Receives Kalamazoo College Distinguished Achievement Award