

**RICHARD M. COOPER, PARTNER**

Richard Cooper is a litigator. Identified as one of "Washington's Top Lawyers" for Food and Drug law by *Washingtonian* magazine (December 2004 and 2009), his principal area of practice is food and drug law, particularly relating to medical products, and including advising, and enforcement (e.g., inspections, warning letters, administrative sanctions, injunction proceedings, and criminal proceedings). He was lead counsel in a commercial arbitration that, in 2007, resulted in an award of more than \$395 million for his client. Other recent and current matters include litigation over a product-related decision by FDA, defense against a claim of false advertising, defense against claims of improper pharmaceutical pricing, and resolution of FDA enforcement actions. As lead counsel, he argued successfully in *FDA v. Brown & Williamson Tobacco Corp.*, 529 US 120 (2000). He has represented clients in congressional and other hearings. His clients have included major pharmaceutical and other consumer products companies.

Mr. Cooper has taught food and drug law at Georgetown University Law Center (1987-92, 1996), has written extensively in the field, and has served on committees, including: Advisory Panel on Strategies for Medical Technology Assessment, Congressional Office of Technology Assessment (1980-81); Committee on Priority Mechanisms, National Research Council, National Academy of Sciences (1980-83); Editorial Advisory Board, *Food & Drug Law Journal* (1981-88, 1992-96), Chairman (1995); Committee on Contraceptive Development, National Research Council, National Academy of Sciences (1987-90); Editorial Advisory Board, *FDA Enforcement Manual* (1993-present); Editorial Advisory Board, *Food Safety Law* (1994); Board of Directors, Food & Drug Law Institute (2000-02); Chairman of the Board, Business Crimes Bulletin (1995-2006).

Mr. Cooper has frequently served as an expert witness on food and drug matters. He also has served as an arbitrator.

His memberships have included: Georgetown University Law Center Supreme Court Institute (2000-present); Haverford College Board of Managers (1997-2009), Co-Chairman, Finance Committee (2000-2009); Board of Directors, Good Shepherd Ministries, Inc., Washington, DC, and member, Executive Committee (2001-2008); Advisory Board, Jelleff Boys and Girls Club, Washington, DC



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**PRACTICE AREAS**

- Administrative Law
- Criminal Defense
- Health Care and Medical Products

**EDUCATION AND HONORS**

- Harvard Law School, J.D., *summa cum laude*, 1969; President, *Harvard Law Review*, volume 82; Sears Prizes for standing first in first-year examinations and second in second-year examinations; First prize for oral argument in first-year moot court competition, spring round
- Oxford University B.A., First Class with Congratulations, 1966; M.A., 1970
- Haverford College, B.A., *summa cum laude*, 1964; Rhodes Scholarship; Danforth Fellowship; Woodrow Wilson Fellowship
- Selected as a one of the Eleven Best Food and Drug Lawyers in Washington, DC by *Legal Times* (September 19, 2005)
- Ranked among "The 75 Best" by *Washingtonian* Magazine (April 2002)
- "AV-Rated" by *Martindale-Hubbell®*

**BAR ADMISSIONS**

- District of Columbia

(1993-2003); Board of Directors, Washington Shakespeare Company (2004-present); Williams & Connolly LLP Executive Committee (1983-84, 1990-91).

## GOVERNMENT SERVICE

- Chief Counsel, United States Food and Drug Administration, 1977-1979
- Special Assistant to James R. Schlesinger and Senior Member, Office of Energy Policy and Planning, Executive Office of the President, 1977
- Law Clerk, Associate Justice William J. Brennan, Jr., United States Supreme Court, 1969-1970

## PUBLICATIONS

- *Response*, 121 Harv. L. Rev. F. 31 (2008)
- *Pharmaceutical Firms Need Single Standard*, The Baltimore Sun, Nov. 22, 2008
- Co-Editor, FOOD AND DRUG LAW AND REGULATION, (FDLI 2008)
- Testimony, *Short-Change for Consumers and Short-Shrift for Congress? The Supreme Court's Treatment of Laws that Protect Americans' Health, Safety, Jobs and Retirement*, Hearing before the Committee on the Judiciary, U.S. Senate (June 11, 2008)
- *The Need for Oversight of Agency Policies for Settling Enforcement Actions*, 59 Admin. Law Rev. 835 (2007)
- *House Passes Attorney-Client Privilege Bill*, Business Crimes Bulletin, December 2007 at 1
- *The Hobbs Act*, National Law Journal, October 15, 2007 at 13
- *Grand Jury Testimony*, National Law Journal, July 30, 2007 at 13
- *Client Communications*, National Law Journal, May 14, 2007 at 13
- *McNulty Memorandum*, National Law Journal, March 5, 2007 at 13
- *Criminal Aspects of Crisis Management*, Communicating in a Healthcare Crisis (Wayne Pines, 2007)
- *Mail Fraud*, National Law Journal, December 18, 2006 at 24
- *Science, Ethics and Economics in FDA Decision-Making: The Legal Framework*, Volume 61 Number 4 Food and Drug Law Journal at 799 (December 2006)
- *DOJ Pressure to Cut Loose Employees Under Investigation*, Business Crimes Bulletin, November 2006 at 1
- *Deferred Prosecution: An Added Technique for Resolving Federal Criminal Investigations of Organizations*, National Legal Center for the Public Interest, Vol. 10, No. 8, August 2006

- United States Supreme Court
- United States Courts of Appeals for the District of Columbia, Fourth, Fifth, Sixth, Ninth, Tenth, Eleventh, and Federal Circuits
- United States District Courts for the District of Columbia, Maryland, and Central District of Illinois

- *The Thompson Memo*, National Law Journal, August 14, 2006 at 12
- *Crime-Fraud Exception*, National Law Journal, June 12, 2006 at 14
- *The Struggle for the 1906 Act in FDA: A CENTURY OF CONSUMER PROTECTION*, (W. Pines ed. FDLI 2006)
- *Nonprosecution Issues*, National Law Journal, April 10, 2006 at 15
- *Employers and Employees*, Business Crimes Bulletin, February 2006 at 1
- *Compliance Committees*, National Law Journal, February 6, 2006 at 13
- *Responding to a Form 483 or Warning Letter: A Practical Guide*, Volume 60 Number 4 Food and Drug Law Journal at 479 (December 2005)
- *Accounting Fraud*, National Law Journal, November 28, 2005 at 14
- *Hotlines*, National Law Journal, September 25, 2005 at 14
- *Business Crime: Work Product*, National Law Journal, September 6, 2004 at 12
- *Limiting §1001's Reach*, National Law Journal, November 8, 2004 at 11
- *Charging Decisions*, National Law Journal, January 17, 2005 at 11
- *Federal Prosecutors Pressuring Companies, Society Will Pay the Price*, Business Crimes Bulletin, August 2004 at 1
- *Handling Violations*, National Law Journal, July 5, 2004 at 11
- *The FCPA*, National Law Journal, May 5, 2004 at 12
- *Honest Services*, National Law Journal, March 1, 2004
- Panel Discussion: *FDA and the First Amendment* (The Federalist Society), October 25, 2002, pp. 39-64.
- *Grand Jury Secrecy*, National Law Journal, August 20, 2001
- *Business Crime: Raising the stakes*, National Law Journal, June 18, 2001
- *Objectively Reasonable Interpretation Defense In Fraud Prosecutions Under Regulatory Statutes*, Business Crimes Bulletin, May 2001
- *Business Crime: Computer fraud*, National Law Journal, Feb. 26, 2001
- *The WLF Case Thus Far: Not With a Bang, But a Whimper*, 55 Food & Drug L.J. 4 (2000)
- *Business Crime: Corporate caution*, National Law Journal, May 15, 2000
- *Courts Refine Elements of Fed. Fraud Crimes*, Business Crimes Bulletin, Apr. 2000
- *Business Crime: Circuit split - again*, National Law Journal, Feb. 28, 2000
- *Business Crime: A calculus of risks*, National Law Journal, Nov. 29, 1999

- *Business Crime: Regarding gratuities*, National Law Journal, Sept. 27, 1999
- *Business Crime: The fiduciary client*, National Law Journal, July 19, 1999
- *Circuits Split Over 'New' RICO*, Business Crimes Bulletin, July 1999
- *Criminal Law: Self-incrimination*, National Law Journal, May 24, 1999
- *Business Crime: Talking to the press*, National Law Journal, Apr. 19, 1999
- *Criminal Law: Independent Counsel*, National Law Journal, Feb. 1, 1999
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- *Business Crime: Perjury Expanded*, National Law Journal, Nov. 23, 1998
- *Criminal Law: Grand Jury Leaks*, National Law Journal, Oct. 12, 1998
- *Reporting a Rival's Violation: The Payoff and Perils of Peaching*, Business Crimes Bulletin, July 1998
- *Separate Civil and Criminal Penalties Are Now OK*, Business Crimes Bulletin, Jan. 1998
- *The Philosophy of Food and Drug Law* in A PRACTICAL GUIDE TO FOOD AND DRUG LAW AND REGULATION (Kenneth R. Piña & Wayne L. Pines, eds.) (FDLI 1998)
- Co-Editor, FUNDAMENTALS OF LAW AND REGULATION, Vol. I: AN IN-DEPTH LOOK AT FOODS, VETERINARY MEDICINES, AND COSMETICS, and Vol. II: AN IN-DEPTH LOOK AT THERAPEUTIC PRODUCTS (FDLI 1997)
- *Is It Always Smart for a Company to Let Employees Take the Rap?*, Business Crimes Bulletin, Oct. 1997, at 9 and The Corporate Counsellor, November 1997
- *Taking Steps Against Corporate Crime: An Approach After Caremark*, Business Crimes Bulletin, Jan. 1997
- *Vicarious Criminal Liability: Bad Law that Should Be Changed*, Business Crimes Bulletin, Oct. 1996
- *Criminal Investigation as Civil Litigation by Other Means*, Business Crimes Bulletin, May 1996
- *Advice You Can Use on Advice-of-Counsel Defense*, Business Crimes Bulletin, Nov. 1995
- *Criminalizing Corporate Record-Keeping*, Business Crimes Bulletin, Dec. 1994
- *Corporate Regulatory Crimes and the Sentencing Revolution*, Business Crimes Bulletin, Apr. 1994
- *Unapproved Uses of Drugs: An Analysis and Some Proposals*, 49 Food & Drug L.J. 4 (1994)
- *Criminal Aspects of Crisis Management*, In WHEN LIGHTENING STRIKES: A HOW-TO CRISIS MANUAL WITH CLASSIC CASE STUDIES (Wayne L. Pines, ed. 1994)
- *Medicare/Medicaid Anti-Kickback Statute: Too Broad and Too Narrow*, Business Crimes Bulletin, Nov. 1994

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- *Some Effects of the Clinton Health Care Reform Proposals on Regulated Aspects of the Pharmaceutical Industry*, 24 Seton Hall L. Rev. 1260 (1994)
- *Some Problems of Outcomes Studies: Data Access, Conflicts of Interest, and Peer Review*, 58 J. Ass'n of Food & Drug Off. 36 (1994)
- *Triage for the FDA's Medical-Device Morass*, Legal Times, April 19, 1993
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- *Marketing "Violations"*, 47 Food & Drug L.J. 155 (1992)
- *The Food and Drug Administration's Authority to Regulate Miscellaneous Statements by Pharmaceutical Manufacturers*, 7 J. Pharm. Mktg. & Mgt. 99 (1992)
- Editor, FOOD AND DRUG LAW (FDLI 1991)
- *History of Health Claims Regulation*, 45 Food Drug Cosm. L.J. 655 (1990) (co-author)
- *Proving the Safety and Effectiveness of a Nerve Gas Antidote: A Legal View*, IRB, July/Aug. 1989
- *For AIDS Inoculants, Ounce of Pre-emption Worth a Pound of Cure*, Legal Times, June 6, 1988
- *Clinical Data Under Section 510(k)*, 42 Food Drug Cosm. L.J. 192 (1987) *AIDS Vaccines: Liability Concerns*, 53 ASM News 484 (1987)
- *Health Claims on Foods -- Reflections on the Food/Drug Distinction and on the Law of Misbranding*, 44 Am. J. Clin. Nutrition 560 (1986)
- *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 Food and Drug L.J. 233 (1986)
- *Stretching Delaney Till It Breaks*, Regulation, Nov./Dec. 1985
- *Saccharin -- Of Risk and Democracy*, 40 Food Drug Cosm. L.J. 34 (1985)
- *Medical Device Regulations Are Vague, Perplexing*, Legal Times, Dec. 3, 1984
- *Polychlorinated Biphenyls -- Of Risks and Benefits*, 39 Food Drug Cosm. L.J. 240 (1984)
- *Laetrile -- Of Choice and Effectiveness*, 38 Food Drug Cosm. L.J. 417 (1983)
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- *Responding to a Health Crisis*, 23 J. Occupational Medicine 705 (1981)
- *Scientists and Lawyers in the Legal Process*, 36 Food Drug Cosm. L.J. 9 (1981)

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- *A Time to Warn and a Time to Ban*, in BANBURY REPORT 6: PRODUCT LABELING AND HEALTH RISKS (1980)
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- *Unofficial Customary Courts*, Law Development Centre Monthly Bulletin 175 (No. 146, 1971)
- *Uganda's Law Development Centre*, Review of International Commission of Jurists 33 (No. 7, 1971)
- *Note, Procedural Due Process at Judicial Sentencing for Felony*, 81 Harv. L. Rev. 821 (1968)