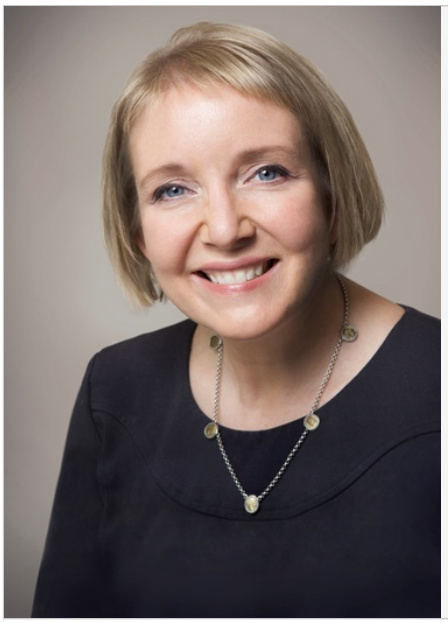
Committee on Energy and Commerce
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Coleen Klasmeier		
2. Your Title: Attorney		
3. The Entity(ies) You are Representing: Medical Information Working Group		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	Yes	No X
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2015. Only grants, contracts, or payments related to the subject matter of the hearing must be listed. None		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature: [redacted] Date: [redacted]

SIDLEY



PARTNER

Coleen Klasmeier

Food, Drug and Medical Device Compliance and Enforcement
Food, Drug and Medical Device Regulatory

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WASHINGTON, D.C. [redacted]

COLEEN KLASMEIER leads the firm's Food, Drug and Medical Device Regulatory practice within the global Life Sciences team, managing matters on behalf of leading biopharmaceutical, medical technology, and food and consumer product companies.
Since joining Sidley from the Office of the Chief Counsel at the Food and Drug Administration in 2005, Coleen has concentrated her practice on FDA litigation and dispute resolution, and on regulatory strategy and risk management. She has been deeply involved as FDA regulatory counsel in defending numerous off-label marketing investigations, as well as in a wide variety of product liability, consumer fraud, Hatch-Waxman, criminal, and appellate matters on behalf of life sciences industry clients.

Through Coleen's leadership, the firm's FDA regulatory practice has grown into a full-service group that is frequently recognized in legal and industry publications for its significant regulatory experience and in-depth industry knowledge. *USNews* rates the FDA practice as among the nation's very best. *Chambers USA* recognizes Sidley as a leading firm for FDA regulatory work, noting in its 2012 edition that, "This highly regarded firm is applauded for its all-encompassing approach to the various industry sectors within the healthcare and FDA space." In 2011, *Chambers USA* said of the group: "Sidley Austin has developed a successfully integrated healthcare and FDA practice, widely viewed as the premier service provider for some of the leading medical device and pharmaceutical companies. Clients particularly praise its expertise in regulatory compliance . . . ."

Coleen is consistently ranked among the nation's top FDA lawyers. The 2017 edition of *Chambers USA* gave Coleen a band 1 raking and described her as "preeminent," and the 2015 edition described Coleen as a "major force" in the field. Praised by clients for her "broad experience" and attentiveness to client needs, and her "tremendous" and "encyclopedic" knowledge of FDA rules, history, and contacts (*Chambers USA* 2011–2012), Coleen was also named a "Life Sciences Star" in the inaugural edition of *LMG Life Sciences* 2012 and has been highly ranked by The Practical Law Company in *The Cross-Border Life*

Sciences Handbook (2007–2012). Since 2012, Coleen has been recommended by *Who's Who Legal* , which reported in its 2013 edition that she is "tremendously knowledgeable about all aspects of regulation" in the life sciences sector. Coleen is recognized in the 2014–2017 editions of *Best Lawyers* for her FDA practice, and has been included in *The Legal 500 US* (2011, 2013–2016). *Washingtonian* has included Coleen on its list of Washington's Best Lawyers as one of the region's "best legal minds" in the area of Food & Drug Law (2013 and 2009).

Coleen has been an adjunct professor at Northwestern University Law School and taught food and drug law in spring 2014.

REPRESENTATIVE MATTERS

Coleen's experience includes:

- Advising consumer technology companies with respect to potential FDA regulation under the medical device provisions of the Federal Food, Drug, and Cosmetic Act (FDCA);
- Representing innovator biological product developers on matters arising under the Biologics Price Competition and Innovation Act (BPCIA);
- Serving as FDA regulatory counsel to clients evaluating compliance issues under reporting provisions of Corporate Integrity Agreements and related negotiated resolutions of government investigations;
- Successfully representing medical technology and consumer product companies in jurisdictional disputes with FDA, including a successful challenge to an Office of Device Evaluation (ODE) determination under Section 513(g) of the FDCA that a cosmetic product was properly regulated as a medical device;
- Successfully representing general hospital use device manufacturers in disputes with FDA's Office of Regulatory Affairs (ORA) and CDRH arising out of Quality System Regulation (QSR) investigations;
- Serving as FDA counsel in multiple off-label enforcement actions, DOJ investigations (both civil and criminal), and internal reviews for major biopharmaceutical and medical device manufacturers;
- Serving as FDA counsel in numerous litigation matters:
    - *Harkonen v. Dept. of Justice*, 800 F.3d 1143 (9th Cir. 2015) (addressing justiciability of Information Quality Act challenge to statements in DOJ press release announcing fraud conviction);
    - *Pacira Pharmaceuticals Inc et al. v. U.S. Food and Drug Administration et al.*, 1:15-cv-07055 (S.D.N.Y.) (counsel for amicus curiae Medical Information Working Group);
    - *Amarin Pharma Inc. et al. v. U.S. Food and Drug Administration et al*., 1:15-cv-03588 (S.D.N.Y. 2012) (counsel for amicus curiae Medical Information Working Group);
    - *United States v. Harkonen*, 510 Fed. Appx. 633 (9th Cir.) (First Amendment challenge to wire fraud conviction for statements in press release announcing results of Phase III clinical trial), cert. denied, 134 S. Ct. 824 (2013);

- *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) (counsel for amicus curiae Medical Information Working Group);
- *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), aff'd sub nom Cook v. FDA, No. 12-5176 (D.C. Cir. July 23, 2013) (counsel for plaintiffs); and
- *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010) (counsel for amicus curiae Washington Legal Foundation).

- Representing the Medical Information Working Group (MIWG), a coalition of leading manufacturers of biopharmaceutical and medical technology products seeking changes to the FDA rules governing the dissemination of truthful, non-misleading information about off-label uses;
- Handling FDA dispute resolution proceedings on behalf of manufacturers adversely affected by refusal-to-file and complete response actions for innovative/orphan biopharmaceutical products;
- Assessing manufacturer copy review processes for internal approval of marketing materials;
- Representing manufacturers in Office of Prescription Drug Promotion (OPDP) regulatory letters, inquiries and advisory comment proceedings and advising on promotional issues for brands across therapeutic areas; and
- Representing innovator clients in Hatch-Waxman and other market access matters involving complex-formulation products and drugs with unique risks.

PRO BONO

Coleen was a lead attorney on *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), a high-profile pro bono case filed against the Food and Drug Administration on behalf of death row prisoners from Arizona, California and Tennessee over the importation into the United States of a misbranded and unapproved lethal injection drug, sodium thiopental. Coleen has also represented the Skin Cancer Foundation and the Spina Bifida Association, and her team is deeply involved in Sidley's Emerging Enterprises Pro Bono Program.

MEMBERSHIPS AND ACTIVITIES

In addition to serving as the leader of Sidley's Food, Drug and Medical Device Regulatory practice, Coleen is a member of the firm's Executive Committee and Diversity Committee. She also chairs the Washington, D.C. Practice Development Committee.

Coleen is a member of the Washington Legal Foundation's Legal Policy Advisory Board. She also is past chair of the Food and Drug Committee of the American Bar Association's Section on Administrative Law and Agency Practice. Coleen formerly served on the Center for Communications Compliance Advisory Board. Her memberships include the FDA Alumni Association, DIA, Women in Bio, and the Food and Drug Law Institute.

PUBLICATIONS

Coleen has been quoted in a wide variety of trade and lay media, including the *Associated Press*, *ABC News*, *Business Week*, *Bloomberg*, *Legal Times, Reuters* and *The Wall Street Journal*. Her work has been published in legal and policy journals and has been cited in *FTC v. Avrom Boris Lasarow*, File No. 132-3210 (February 23, 2015) (dissenting statement), and by the Second Circuit in the 2012 *Caronia* decision involving First Amendment limitations on FDCA misbranding prosecutions. *United States v. Caronia*, 703

F.3d 149 (2d. Cir. 2012).

Coleen is the author of *FDA Advertising and Promotion Manual* (with Wayne Pines) and numerous other publications that include:

- "Policy Options for Off-Label Communication: Supporting Better Information, Better Evidence, and Better Care," Duke-Margolis Center for Health Policy (February 2016) (with Gregory W. Daniel, Morgan H. Romine, Jeff Allen, Nicholas Bagley, Amy Comstock Rick, Mark B. McClellan, Sarina E. Coates, Joy Liu, Peter Pitts, Marc Scheineson, Richard L. Schilsky)
- "Why The FDA's Ban on Off-Label Promotion Violates the First Amendment," in *FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies* (Holly F. Lynch & I. Glenn Cohen, eds. Columbia University Press 2015) (with Martin Redish)
- "Why Your Phone Isn't as Smart as It Could Be," *The Wall Street Journal* (August 7, 2014) (opinion, with Scott Gottlieb)
- Chapter 36 – USA, The International Comparative Legal Guide to: Pharmaceutical Advertising 2013, Global Legal Group Ltd., London (with Maura Martin Norden)
- "Litigation, Products Liability, and Preemption," *PLI's Medical Devices Law and Regulation Answer Book* (2013) (with Rebecca K. Wood)
- "Risk-Benefit Assessment in a Cohort of New Drug Applications," (November 12, 2012) (with Torrey Cope)
- "Congress Should Clarify The Circumstances Under Which Drug Makers Can Communicate Results On Comparative Effectiveness," *Health Affairs*, Vol. 31, No. 10 (October 2012)
- "Alternative Substantiation Standards for Promotional Claims," *FDLI Update*, Advertising and Promotion Issue (September|October 2012) (with Maura Norden)
- "The FDA Wants to Regulate Your Cells," *The Wall Street Journal* (August 8, 2012) (opinion, with Scott Gottlieb)
- *FDA Regulation of Off-Label Promotion: An Answer* (February 5, 2012)
- *NDA Approval Under FDCA Section 505(b)(1) Based on Effectiveness Data from One Clinical Trial* (January 10, 2012) (with Torrey Cope)
- "Off-Label Prescription Advertising, the FDA and the First Amendment: A Study in the Values of Commercial Speech Protection," *American Journal of Law & Medicine*, Volume 37, Numbers 2&3 (2011) (with Martin H. Redish)
- "Comparative Effectiveness Research: The Need for a Uniform Standard," AEI, No. 6 (June 2009) (with Scott Gottlieb)

EVENTS

Coleen is a nationally recognized speaker and regularly lectures on regulatory issues. Her recent and upcoming speeches include:

- Speaker, PharmedOut 2017 Conference, "The Limits of FDA-Approved Labeling and the Evolving

Informational Needs of a Changing Healthcare System," June 15-16, 2017, Washington, D.C.

- Panelist, ISPOR 22nd Annual International Meeting, "FDAMA Section 114 Has Been Replaced By Section 3037 Of The Cures Act: Now What?," May 20-24, 2017, Boston, MA
- Moderator, "Truth and Non-Misleading Communications and Recent First Amendment Cases," The Seventeenth Annual Pharmaceutical and Medical Device Compliance Congress, October 19-21, 2016, Washington, D.C.
- Panel Moderator, "Bay to Beltway: Why Regulatory Strategy Matters to Innovators," Bay Area Life Sciences Roundtable: *Crossing the Technology/Life Sciences Divide*, April 13, 2016, San Francisco, CA
- Panelist, "Potential Policy Solutions for an Improved Communication Process," Off-Label Communication in 2016: Meeting Information Needs through New Policy Options, Duke-Margolis Center for Health Policy, February 18, 2016, Washington, D.C.
- Discussant, "The Promotion of Medical Products in the 21st Century," FDLI's Food and Drug Law Journal Symposium: Constitutional Challenges to FDA Law & Regulation, October 30, 2015, Georgetown University Law Center, Washington, D.C.
- Speaker, "When Does FDAMA Section 114 Apply and How Might It Change? Ten Case Studies," Webinar, June 2, 2015, Washington, D.C.
- Panelist, Manhattan Institute for Policy Research Briefing, "Off-Label Shouldn't Mean Off-Limits: Advancing Information to Save Lives," October 8, 2014, Washington, D.C.
- Speaker, "What's Next? on the First Amendment Webinar Series," July 8, 2014, Washington, D.C.
- Chair and Speaker, "FDA Programs to Encourage Innovation: Maximizing the Opportunities and Confronting the Challenges of New Product Development," and "FDA Drug Claims Substantiation after IMS and Caronia: Will Court Scrutiny Based on the First Amendment Lead to Change in Current Policy and Practice?" 50th Annual Meeting of the Drug Information Association (DIA), June 15-19, 2014, San Diego, CA
- Chair and Speaker, "Can We Handle the Truth: Roundtable Discussion," Biostatistics and FDA Regulation: The Convergence of Science and Law Symposium, May 20, 2014, Harvard Law School, Cambridge, MA
- Speaker, "*U.S. v. Caronia*, One Year Later: The First Amendment and Federal Oversight of Off-Label Drug and Device Promotion," Washington Legal Foundation Media Briefing Series, January 16, 2014, Washington, D.C.
- Speaker, "Beyond the 'Label': Promotion in the Facebook Era," Ninth Annual FDA/CMS Summit for Biopharma Executives, December 12, 2013, Washington, D.C.
- Session Leader and Speaker, "Prescription Drug Promotion: The Year in Review," 2013 Annual Meeting of the Regulatory Affairs Society (RAPS), October 1, 2013, Boston, MA
- Speaker, "Handling the Truth: Conflict Between Free Speech and Off-Label Promotion," DRI's 29th Annual Drug and Medical Device Seminar, May 16-17, 2013, New York, NY

- Speaker, "A Disruptive Approach to Fundamental Reform," 2013 New Paradigms Conference, January 8-10, 2013, San Francisco, CA
- Speaker, "Regulatory Approaches to Benefit and Risk: A Global Perspective," CHI Annual Meeting, November 8, 2012, Foster City, CA
- Moderator, "Comparative Effectiveness: Communicating Research Results to Make a Difference," FDLI Advertising and Promotion Conference, October 1-2, 2012, Washington, D.C.
- Moderator, "Different Perspectives on Off-Label Promotion," FDLI's The Intersecting Worlds of Drug, Device, Biologics, and Health Law Conference, May 21-22, 2012, Washington, D.C.
- Speaker, George Mason University Law School Third Annual Attorneys General Education Program (AGEP) Public Policy Conference, May 3, 2012, Washington, D.C.
- Speaker, BIO General Counsels Committee Meeting, April 12-13, 2012, San Francisco, CA
- Speaker, FDA Commissioners' Fellows, "FDA History and Alumni Perspectives," April 3, 2012, Silver Spring, MD
- Speaker, Washington Legal Foundation Web Seminar Series, "ENDGAME?: The Solution to Drug and Device Makers' Off-Label Problem," March 14, 2012, Washington, D.C.
- Speaker, "Best Practice Insights on Managing the Risks of Off-Label Promotion," C5's Seventh Conference on EU Pharma Law and Regulation, February 22-23, 2012, London, UK
- Speaker, "Navigating Regulatory Hurdles: A Comparison of US v EU Regulatory Environment and Suggestions for FDA Reform," New Paradigms to Fund & Move Drug Development, January 11-12, 2012, Marines' Memorial Club & Hotel, San Francisco, CA
- Speaker, "New Initiatives to Enhance Regulatory Clarity," CBI's 13th Annual Guidelines for Disseminating Off-Label Information, October 17-18, 2011, The Westin Arlington Gateway, Arlington, VA
- Plenary Speaker, "Spotlight on Recent and Pending Labeling Related Cases – Including *Matrixx v. Siracusano* and *PLIVA v. Mensing*," FDANews 2nd Annual Pharmaceutical Labeling Summit, September 26, 2011, National Press Club, Washington, D.C.
- Moderator, "Whose Job Is It? Best Practices for Effective Interdisciplinary Promotional Review," FDLI's Advertising & Promotion Conference, September 26, 2011, The Capitol Hilton, Washington, D.C.

SERVICES

APA Litigation & Regulatory Strategy in the Pre-Litigation Phase
Biotechnology
Clinical Diagnostic Laboratories and Genetic Testing
Clinical Trials
Compliance Counseling - FDA
Digital Health
FDA Enforcement
Food, Drug and Medical Device Compliance and Enforcement
Food, Drug and Medical Device Regulatory
Good Manufacturing Practice
Healthcare Enforcement
Healthcare Public Policy and Governmental Affairs
Life Sciences Transactions
Medical Devices
Pharmaceuticals
Risk Assessment and Mitigation for M&A and Investments in Life Sciences Industry
Risk Mitigation: U.S. Sales & Marketing

INDUSTRIES

Life Sciences

ADMISSIONS & CERTIFICATIONS

U.S. Supreme Court

U.S. Court of Appeals, D.C. Circuit

U.S. District Court, District of Columbia

District of Columbia

Maryland

EDUCATION

Boston University School of Law, J.D., 1996 (*magna cum laude*)

McDaniel College (formerly Western Maryland College), B.A., 1993 (*summa cum laude*)
