THOMPSON COBURN LLP

Diane Romza-Kutz

Counsel

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PRACTICES

- FDA Regulatory
- Food & Beverage
- Health Care
- Cannabis
- Life Sciences

EDUCATION

- Loyola University Chicago School of Law, LL.M, 1994
- Northern Illinois University College of Law, J.D., 1981
- Western Illinois University, B.S., 1978

ADMISSIONS

- Illinois

AFFILIATIONS

- American Health Lawyers Association (AHLA), Vice Chair, Committee on Managed Care and Integrated
- Delivery Systems
- Illinois Chamber of Commerce, Executive Healthcare Council

Diane helps life sciences companies develop new products and bring them to market while proactively addressing the regulatory land mines that can delay or destroy the path to profits.

She works with life science companies in the businesses of food and food ingredients, dietary supplements, animal health, prescription/over-the-counter drugs, medical devices, tobacco and agribusiness, and biologics — clients that all face a similar framework of crisscrossing federal, state and local regulations.

Diane partners with her clients to craft sound business strategies that account for the complex interplay among regulators. Her discerning knowledge of these regulatory agencies gives her clients an edge in gaining and maintaining marketplace dominance. Diane closely monitors and counsels clients throughout a product's lifecycle on matters pertaining to the:

• U.S. Food and Drug Administration
• U.S. Department of Agriculture
• Federal Trade Commission
• Drug Enforcement Administration

Diane also tackles many other legal business issues that arise within her clients' operations. Notably, she negotiates global licensing agreements and directs litigation involving pre-emption claims, misbranding, duty to warn, and licensing and infringement.

As a member of Thompson Coburn's cannabis practice, Diane counsels cannabis businesses on how to navigate the tension between the federal government's regulatory position and states that have legalized marijuana use.

Although she serves a multifaceted group of clients, Diane holds special affinity for animal health. She is a self-described animal lover and a proud horse owner. She witnessed first-hand how life sciences technology has the power to transform lives when one of her own horses was given an extended life through the use of stem cells. To that end, Diane is proud to have served as regulatory counsel to two animal health companies in their

RECOGNITIONS

- Recipient, JD Supra "Readers' Choice Award," 2018
  - Recognized for being a top author for life sciences
- Chicago Business Journal Woman of Influence, 2015
- Listed in Illinois Super Lawyers, 2006-2015

COMMUNITY

- Chicago Police Department, Task Force on Victimization of Disabled Persons
- Cook County State's Attorney's Office, Task Force on Mass Molestation
- Illinois Attorney General Task Force on development of a Comprehensive Health Insurance Program for the Chronically Ill

public offerings, and continues to act as regulatory counsel to both companies.

Experience

- **Biotech/Pharma**

  Counsels clients on national and international life sciences regulatory matters, including FDA and FTC issues; post-marketing concerns; clinical trials; global licensing deals; labeling concerns; product marketing and advertising; filing of New Drug Applications (human and animal); product recalls (both voluntary and involuntary); FTC and FDA investigations into misbranding, adulterated products; mislabeling and marketing claims; creating, enacting and training in corporate compliance programs; in-and-out licensing strategies; evaluating projects for venture investments; alternative dispute resolution; and structuring joint ventures. She also counsels clients on USDA and DEA compliance and regulatory matters.

  Defends pharmaceutical, biotechnology and medical device companies in cases involving product liability claims, pricing issues, False Claims Act matters, contract and fraud allegations, consumer and third-party class action cases. Cases involved multidistrict litigation, whistleblower claims, advertising lawsuits, marketing disputes with regulatory bodies, off-label promotions and failure-to-adequately-warn claims (including consumer class actions).

  Represents high-technology and life science companies in intellectual property matters, including licensing agreements and infringement actions.

- **Medical Devices/Bioinformatics**

  Counsels clients on registration requirements, 510(k) and PMA applications and compliance with other FDA regulations.

  Counsels clients on the FDA requirements related to software, security of that software, and other cybersecurity risks as outlined by the FDA.

- **Health Care**

  Litigates on behalf of traditional healthcare clients on claims arising from regulatory and contractual issues, including, but not limited to, False Claims Act cases, noncompetition disputes and certificate-of-need actions.

  Represents hospital networks, other health-system providers and pharmaceutical companies in a wide range of civil and criminal healthcare matters, including class action cases and government investigations.

  Creates joint ventures for corporate healthcare providers, drafts hospital compliance programs and trains clients on their implementation, reviews and drafts policies and procedures, negotiates business agreements for hospitals and advises on economic credentialing.

- **Animal Health**

  Served as Food and Drug Administration (FDA), United States Department of Agriculture (USDA) and Federal Trade Commission

(FTC) regulatory counsel to animal health companies in their regulatory filings and compliance programs.

Served as FDA regulatory counsel for international and domestic animal health companies as they prepared for US initial public offerings (IPOs).

Served as intellectual property and licensing counsel for a domestic animal health company as it prepared for IPO.

Presentations

- Establishing Protocols for the Next Wave of FSMA Rule Implementation for Animal Feed, Pet Food and Animal Drug Manufacturers Animal Health: Veterinary Drugs, Therapeutics, and Animal Food, New York September 2016
- "Mobile Medical Apps and FDA's New Cybersecurity Guidance: It's a New World" Thompson Coburn CLE March 2016
- Guest lecturer (FDA matters) Loyola University Chicago LL.M. program
- "Startup Workshop: Understanding the Royalty Agreement"; MedCity Invest, Chicago, April 2016
- "Litigation Amid a Cloud of Crisis: Aligning Legal Strategy with Reputation Management"; Association of Corporate Counsel Chicago, December 2015
- "Opportunities at the Intersection of Animal and Human Health"; BIO-Europe, Munich, Germany, November 2015
- "Animal Health and Veterinary Medicines 101: Primer on the legal and regulatory landscape for medicines and therapeutics for companion animals and livestock"; ACI: Animal Health and Veterinary Drugs and Therapeutics, September 2015
- Spotlight on Licensing: Navigating the Regulatory Environment; Missouri LES meeting, Summer 2015
- Animal Health IPOs: Regulatory issues to Consider in a Capital Raise or IPO; Client Update, September 2014
- Avoiding and Limiting Risks in Licensing Agreements; Client Update, Fall 2015
- Cutting Dietary Supplement Red Tape; Client Update, Fall 2014

Publications

- "Medical devices and cybersecurity: FDA calls for comprehensive risk management programs" *Life Sciences Decoded Blog,* March 2016
- "FDA-regulated industries: Plan now for these changes in 2016" *Life Sciences Decoded Blog,* January 2016
- "Creating Shareholder Value Through M&A in the Life Sciences Sector"; *Financier Worldwide,* February 2016
- "FDA Cracks Down on the Dietary Supplement Industry"; *Law360,*

November 2015

- "The FDA's Risk-Based Approach To Medical App Enforcement"; *Law360,* September 2015
- "FDA Complete Response Letters: The design v. reality of FDA's response to drug applications"; *Client Update,* January 2015
- "Managing the Changing Drug Compounding Regulatory Landscape"; *AHLA Connections,* October 2014
- "FDA cGMP Rule Expected for Animal Feed Manufacturers"; *Animal Pharm,* July 2014
- "The Challenging Landscape of Mobile Medical App Regulation"; *Client Update,* June 2014
- "The Nutrition Facts Panel Gets a Makeover and Food Manufacturers Get the Bill"; *Client Update,* June 2014