NELSON HARDIMAN
HEALTHCARE LAWYERS


**Ariella (Cohen) Coleman**
Attorney

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### Admissions

Not admitted to practice in California
Admitted in District of Columbia, New Jersey, and Pennsylvania (inactive)

### Affiliations

American Bar Association
D.C. Bar Association
The American Health Lawyers Association

### Education

Drexel University Thomas R. Kline School of Law, J.D.
University of Maryland, B.A.

## PROFILE

Blending a regulatory background with strong experience in healthcare law and policy, Ariella Coleman excels at finding cutting-edge solutions to healthcare and life sciences challenges. She is a creative problem-solver whose experience encompasses a range of health law and policy issues, including a focus on products regulated by the Food Drug Administration (FDA) under the Food Drug and Cosmetics Act (FDCA) and related compliance issues arising from innovation. Ariella's background in advocacy and public policy give her a keen understanding of key industry topics across the full range regulatory concerns of paramount importance to healthcare and life sciences clients.

**Deep Experience in FDA and Direct-to-Consumer Products and Services**

The pandemic-driven acceleration of telemedicine has spurred renewed interest in the heavily regulated arena of direct-to-consumer products and services. Leveraging her legislative and policy experience with FDA-regulated products and compliance, Ariella works closely with clients in developing regulatory strategy and the pathway for new products and services, including emerging diagnostics and therapeutic technologies. She played a role in the passage of the Over-the-Counter (OTC) Drug Monograph Reform legislation, offering technical assistance on draft legislation and negotiating with Congress, FDA, and other stakeholders to craft legally sound public policy. Ariella's work deciphering the complexities of the outmoded OTC monograph system helped pave the way for this important legislation that makes it easier for firm clients to bring innovative and safe OTC products to market.

**Extensive Knowledge of Healthcare**

In addition to her FDA regulatory focus, Ariella has a strong working knowledge of transfusion medicine and biotherapies. She has worked to ensure that blood bank policies and practices comply with FDA regulations, the Health Information Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), and applicable employment and tax laws across various states. Ariella has advised clients on multi-state business and regulatory compliance with Medicare requirements and bankruptcy requirements. She provides advice and counsel on fraud and abuse investigations and all aspects of hospital compliance and risk management, including updates to existing policies and transaction documents.

**Focus on Solutions**

Adept at navigating complex regulatory issues around FDA, HIPAA, and HITECH compliance, Ariella harnesses her knowledge and experience with healthcare law to evaluate options for efficiently making new healthcare products and services available to patients who need them. Ariella provides support to clients seeking to use emerging technology to deliver medical solutions involving telehealth, direct-to-consumer products, and wellness. She is a problem-solver who works to clear regulatory hurdles effectively, both preventing and responding to any problems that might arise. Ariella is fiercely committed to making the world a healthier place by sorting out the policies that govern the healthcare industry.

**Life Outside the Firm**

Ariella previously founded The Wellness Esquire, seeking to shift legal culture to recognize and value the connection between wellbeing and success. Outside of work, she enjoys easy access to nearby beaches, recharging on nature hikes with her husband, and relaxing by playing her baby grand piano.

## EXPERIENCE

- OTC Monograph Reform Legislation. Redlined Over-the-Counter (OTC) Drug Monograph Reform legislation replacing 40+ year-old language; the new law, included in CARES Act, increases resources for the Center for Drug Evaluation and Research and allows FDA to respond more quickly to safety concerns.
- Off-Label Promotion. Applied FDC&A and FDA Guidance Documents to legislative efforts – e.g., analyzed scientific research regarding off-label use of prescription drugs approved for particular indication, reviewed applicable regulations, and submitted comments to FDA docket.
- Insanitary Conditions at Compounding Facilities**.** Applied FDC&A and FDA Guidance Documents to legislative efforts – e.g., analyzed scientific research regarding injuries sustained from drug compounding performed under insanitary conditions, reviewed applicable regulations, and submitted comments to FDA docket.
- Prepared publishable memoranda and white papers for C-Suite on key health topics, including Zika Virus and FDA authority over human donor milk.
- Conducted 50-state and international research on blood donor age requirements and rules regarding LGBTQ+ donation of blood.
- Researched and drafted comprehensive memoranda regarding fraud and abuse, Conditions of Participation and Payment, bankruptcy, HIPAA, and agency law.
- Partnered with Chief Compliance Officer and Associate General Counsels on fraud and abuse investigations and all aspects of hospital compliance and risk management.
- Wrote new and updated existing hospital policies and transaction documents for hospital system affiliates.