

Krista Hessler Carver

Partner

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About ^

Krista Carver co-chairs Covington's global Food, Drug, and Device Practice Group and the firm's Life Sciences – Pharmaceutical and Biotechnology Industry Group. Drawing on her more than 18 years of experience at the firm, she provides strategic and practical advice to clients on an array of FDA regulatory issues, including those that intersect with other areas such as healthcare. Ms. Carver also assists clients with advocacy before FDA, including formal dispute resolution and citizen petitions, and maintains an active policy practice addressing legislative issues surrounding amendments to the Federal Food, Drug, and Cosmetic Act and related laws. *Chambers USA* reports that Krista “is a brilliant lawyer with deep technical expertise that she is able to boil down clearly and succinctly,” and that she “is incredibly impressive in biosimilars issues and biologics,” per *Chambers* sources. Krista co-chairs Covington's **IRA Task Force**.

Krista's areas of focus include:

- Inflation Reduction Act;
- Biosimilars;
- Hatch-Waxman regulatory issues;
- Orphan-drug designation and exclusivity matters;
- Pediatric Research Equity Act and Best Pharmaceuticals for Children Act;
- Digital health;
- Gene therapies and human cellular, tissue, and cellular- and tissue-based products;

- Risk evaluation and mitigation strategies (REMS), pharmacovigilance, postmarketing study requirements; and the CREATES Act; and
- Clinical trial and submission issues including real-world evidence, decentralized clinical trials, and diversity in clinical trials.

Areas of Expertise

- Regulatory and Public Policy >
- Food, Drug, and Device >
- Pharma and Biotech >
- Digital Health >
- Life Sciences >

Representative Matters



Credentials



News and Insights



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