

John T. Bentivoglio

Skadden

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Health Care Enforcement



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Education

J.D., Georgetown University
Law Center

B.A., University of California, Berkeley

Bar Admissions

District of Columbia
Maryland

Government Service

U.S. Department of Justice: Associate
Deputy Attorney General (1998-2000);
Counsel to the Deputy Attorney
General & Special Counsel for Health
Care Fraud (1997-1998); Trial Attorney,
Criminal Division (1996-1997)

Committee on the Judiciary, U.S.
Senate: Professional Staff Member
(1988-1992); Legislative Assistant
(1986-1988)

John Bentivoglio represents pharmaceutical, medical device and biotechnology manufacturers in criminal, civil and administrative enforcement actions by the U.S. Department of Justice, state attorneys general and other agencies. He has negotiated successful resolutions of such matters for Allergan, Calloway Laboratories, Jazz Pharmaceuticals, Merck & Co., Otsuka Pharmaceuticals and Serono, among others. He also has counseled more than a dozen companies on the negotiation and implementation of Corporate Integrity Agreements. In addition to assisting companies in enforcement actions, he regularly advises clients on compliance program issues and on federal and state anti-kickback and false claims statutes, FDA advertising and promotional rules, and Medicare and Medicaid regulatory issues.

From 1997-2000, he served as associate deputy attorney general and special counsel for health care fraud at the DOJ, where he advised the attorney general and deputy attorney general on national enforcement initiatives, health care investigation and prosecution policies, and interagency coordination. From 1996-1997, he was a special assistant to the assistant attorney general, Criminal Division. Earlier in his career, Mr. Bentivoglio served as a professional staff member to Sen. Joseph R. Biden Jr., chairman, Committee on the Judiciary.

Mr. Bentivoglio repeatedly has been selected for inclusion in *Chambers USA: America's Leading Lawyers for Business* and *The Best Lawyers in America*, and was recognized as a 2018 BTI Client Service All-Star by The BTI Consulting Group. He also was selected for inclusion in *Who's Who Legal: Life Sciences* and repeatedly named as a Star in *LMG Life Sciences*.

Mr. Bentivoglio is an active volunteer firefighter and EMT with the Bethesda-Chevy Chase Rescue Squad in Bethesda, Maryland.

Speeches

Food and Drug Law Institute Advertising and Promotion Conference 2017 (Moderator), Washington, D.C. (September 2017);

"DOJ and OIG Enforcement Update," Pharmaceutical Compliance Forum, Philadelphia (March, September 2016);

17th Annual Pharmaceutical and Medical Device Compliance Congress, Washington, D.C. (October 2016); and

"AUSA Roundtable: Hot Topics in DOJ Enforcement in the Pharmaceutical Industry" (Moderator), Pharmaceutical Compliance Forum, Washington, D.C. (November 2014-2016).

Selected Publications

"Inside DOJ's Recent Charitable Copay Foundation Settlements," *Law360*, April 22, 2019

"The Responsible Corporate Officer Doctrine: Protections are Needed Despite DOJ's Cautious Approach," *Food and Drug Law Institute's Update*, December 2018

"10 Steps to Modernizing Corporate Integrity Agreements," *Law360*, June 20, 2018

"3 New Settlements Highlight DOJ Scrutiny of Device Makers," *Law360*, April 4, 2018

“Enforcement and Litigation Strategies: Skadden’s Eighth Annual Pharmaceutical, Biotechnology and Medical Device Seminar,” *Skadden, Arps, Slate, Meagher & Flom LLP*, March 29, 2018

“Health Care Investigation Trends: Corporate Integrity Agreements No Longer a Given,” *Skadden, Arps, Slate, Meagher & Flom LLP*, March 26, 2018

“As Congress Struggles With ACA Repeal, Trump Administration Moves Forward With Regulatory Reform,” *Wolters Kluwer’s Health Law Daily*, February 7, 2018

“As Congress Struggles With ACA Repeal, Trump Administration Moves Forward With Regulatory Reform,” *Skadden’s 2017 Insights*, January 23, 2018

“Will Life Sciences Companies Face More Scrutiny in 2018?” *Law360*, January 9, 2018

“A Dialogue With Corporate Counsel: Skadden’s Seventh Annual Pharmaceutical and Medical Device Seminar,” *Skadden, Arps, Slate, Meagher & Flom LLP*, December 5, 2017

“Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs,” *Skadden, Arps, Slate, Meagher & Flom LLP*, September 28, 2017

“Recent Settlements Suggest Off-Label Cases Aren’t Extinct,” *Law360*, August 30, 2017

“Trends in Corporate Integrity Agreements Reflect New HHS OIG Guidance on Use of Exclusion Authority,” *Skadden, Arps, Slate, Meagher & Flom LLP*, March 13, 2017

“Republicans Chart New Course For U.S. Health Care System,” *Westlaw Journal Insurance Coverage*, March 3, 2017

“FDA Publications Double Down on Agency’s Ability to Prohibit Off-Label Communications, but Narrow Scope of Debate,” *Skadden, Arps, Slate, Meagher & Flom LLP*, February 1, 2017

“Republicans Chart New Course for US Health Care System,” *Skadden’s 2017 Insights*, January 30, 2017

“Inciting Innovation in Drug and Medical Device Development,” *Law360*, December 14, 2016

“The 21st Century Cures Act: FDA Reforms Aim to Spur Innovation in the Pharmaceutical, Medical Device and Health Research Sectors,” *Skadden, Arps, Slate, Meagher & Flom LLP*, December 13, 2016

“Supreme Court Holds That Violations of the False Claims Act’s Seal Requirements Do Not Require Automatic Dismissal,” *Skadden, Arps, Slate, Meagher & Flom LLP*, December 7, 2016

“*Escobar* and the Implied Certification Theory: Initial Cases Raise the Bar on Materiality in False Claims Act Litigation,” *Skadden, Arps, Slate, Meagher & Flom LLP*, November 7, 2016

“Key Takeaways: Fourth Annual Seminar for Pharmaceutical, Biotechnology and Medical Device Companies,” *Skadden, Arps, Slate, Meagher & Flom LLP*, October 24, 2016

“In *Escobar*, Supreme Court Upholds False Claims Act’s Implied Certification Theory,” *Skadden, Arps, Slate, Meagher & Flom LLP*, June 17, 2016

“Financial Relationships Likely To Be Focus In Life Sciences Enforcement And Litigation,” *Skadden’s 2016 Insights - Regulatory Developments, Westlaw Journal Health Care Fraud and Westlaw Next Practitioner Insights*, January 2016; May 18, 2016; April 8, 2016

“Risk Of Future Misconduct Will Guide HHS Investigations,” *Law360*, April 26, 2016

“New HHS OIG Criteria to Guide Resolution of Health Care Investigations,” *Skadden, Arps, Slate, Meagher & Flom LLP*, April 21, 2016

“Supreme Court Permits Use of Statistical ‘Representational Evidence’: Implications for the FCA,” *Skadden, Arps, Slate, Meagher & Flom LLP*, April 4, 2016

“*Amarin* Settlement Erodes Off-Label Promotion Enforcement,” *Law360*, March 11, 2016

“*Amarin* Settlement Order and Vascular Solutions Acquittal Further Erode Off-Label Promotion Enforcement Regime,” *Skadden, Arps, Slate, Meagher & Flom LLP*, March 8, 2016

“Recent Corporate Integrity Agreements Highlight HHS OIG’s Compliance Program Priorities,” *Skadden, Arps, Slate, Meagher & Flom LLP*, February 1, 2016

“Examining Recent Corporate Integrity Agreement Trends,” *Law360*, January 26, 2016