Michael H. Hinckle

Managing Partner, Research Triangle Park Office

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OVERVIEW

Michael Hinckle is the Managing Partner of the firm's Research Triangle Park office. His practice focuses on counseling corporations and individuals on all aspects of FDA regulatory and pharmaceutical pricing matters. His primary efforts are in the area of pharmaceutical, biologic, tobacco, and medical device regulation as well as related corporate transactional activities. His experience includes serving as in-house General Counsel for an international pharmaceutical corporation with responsibilities for all legal activities, regulatory affairs, quality assurance, corporate compliance, and litigation oversight. Michael's experience also includes representing clients before the FDA, FTC, DEA, CMS, and various State Boards of Pharmacy. He has supervised the filing of numerous drug, biologic, tobacco, and device investigational and premarket submissions, Citizen Petitions, and other regulatory filings. On the post-marketing side, Michael has represented his clients on FDA compliance matters including Warning Letters and negotiation of Consent Decrees. His government pricing experience includes advising pharmaceutical manufacturers on issues under the Federal Supply Schedule, the Medicaid Drug Rebate Program, the Veterans Health Care Act, and Section 340B of the Public Health Service Act.

PROFESSIONAL BACKGROUND

Prior to entering private practice, Michael worked as a molecular biologist with the American Type Culture Collection. He then represented various FDA-regulated companies in private practice for 7 years before becoming the Vice President and General Counsel for Synthon Pharmaceuticals, Inc., a position that he held for 5 years. Michael is a frequent lecturer and author on FDA and pharmaceutical industry matters.

PROFESSIONAL / CIVIC ACTIVITIES

- Food and Drug Law Institute
- North Carolina Regulatory Affairs Forum

SPEAKING ENGAGEMENTS

- Biosimilars--The Current Legal Landscape," North Carolina Biotechnology Center, February, 2016

- "FDA Regulation of Generic Drugs and Biosimilars," North Carolina Regulatory Affairs Forum, RAC Certification Course Lecturer, July 2016
- "Surviving an FDA Inspection," North Carolina Biotechnology Center, CLE, January, 2015
- "FDA Regulation of Medical Textiles," Guest Lecturer, North Carolina State University, October, 2014
- "The Biosimilars Act—A Basic Introduction," NC CED Biotech Forum, September 2010
- "Analysis of the Commonwealth Brands and Teva Pharmaceuticals Cases," Food and Drug Law Institute 2010 Annual Meeting, April 2010
- "New Product Development," Campbell University School of Pharmacy, annual lectures on FDA regulatory matters, 2006-2009
- "Preparing for Paragraph IV Challenges - Generic Pre-suit Strategies," CBI, Paragraph IV Conference, October 2008
- "Interpreting Forfeiture Provisions - An Analysis of Recent Cases to Increase Preparedness and Improve Product Strategy," CBI, Paragraph IV Conference, October 2008
- "Protecting the Pharmaceutical Asset," RTP Biotech Day, October 2007
- "Generic Drugs - Patents and Market Exclusivity," Campbell University School of Pharmacy," April 2006
- "Basic FDA Regulatory Law," Campbell University School of Pharmacy, January 2006

EDUCATION

- J.D., George Washington University Law School, 1996 *(with honors)*
- B.S., Radford University, 1987 *(cum laude; Biology)*

ADMISSIONS

- Bar of District of Columbia
- Bar of North Carolina

THOUGHT LEADERSHIP *POWERED BY HUB*

- 5 March 2024, Highlights From FDA Regulatory Developments in Clinical Trials: 2023 Recap and 2024 Forecast
- 29 January 2024, An Overview of the US Food and Drug Administration's Legislative Goals (Part I)
- 1 June 2023, Highlights for Research Institutions and Sponsors in FDA's Recent Draft Guidance on Decentralized Clinical Trials

- 26 September 2022 , Issue-Spotting Hospital Activities that May Trigger FDA Regulatory Oversight
- 15 June 2022, New FDA Draft Guidance Aiming To Prevent Drug Shortages Will Affect Pharmaceutical Manufacturers
- 28 October 2021, What Health Care Providers Should Expect in an FDA Inspection
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part IV: Other Potential Applicable Laws
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers - Part III: FDCA
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part II: HIPAA (Continued) & Additional Important Privacy Considerations
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part I: HIPAA
- June 2020, COVID-19: Paved With Good Intentions – Regulatory Pitfalls to Manufacturing and Marketing COVID-Related Consumer Products
- 24 March 2020, COVID-19: FDA Publishes Enforcement Policies – Ventilator/Respiratory & Remote Patient Monitoring Devices
- 11 February 2019, HHS Issues Proposed Rule to Remove Safe Harbor for Drug Rebates
- 9 August 2018, K&L Gates Triage: REMS…Sharing Is So Hard to Do
- 10 November 2017, Recent FDA Steps to Advance Medical Device Access and Innovation
- 16 October 2017, FDA Announces Public Meetings and Requests Comments on Agricultural Biotechnology Education and Outreach Initiative
- 30 May 2017, 340B Update: Trump Administration Calls for New Legislation and Regulatory Authority; HRSA Delays Regulations on 340B Pricing & Penalties for Drug Manufacturers to October 1, 2017
- 29 March 2017, 340B Update: HRSA Further Delays Regulations on 340B Pricing & Penalties for Drug Manufacturers
- 21 March 2017, Medicinal Products: the EU and the US Mutually Recognize Manufacturing Standards
- 18 January 2017, 340B Update: HRSA Finalizes 340B Pricing & Penalties for Drug Manufacturers
- 22 August 2016, HRSA Releases Proposed Rule Governing the Administrative Dispute Resolution Process for 340B-Related Claims
- 22 October 2015, 340B Orphan Drug Interpretive Rule Struck Down by D.C. District Court: HHS and HRSA Lose In Second Round of Litigation Over 340B Orphan Drug Rules

- 22 June 2015, 340B Update: HRSA Proposes Penalties for Drug Manufacturers that Overcharge Covered Entities
- 21 May 2015, FDA Proposes New Expansive Animal Drug Antimicrobial Reporting Regulations

OTHER PUBLICATIONS

- "Pharma Ruling Broadens Gov't Drug Procurement Options," *Law360*, 24 February 2020
- "Amgen v. Sandoz" *FDLI Top Cases of 2015, Annual Meeting Materials*, April 2016
- Chapter in "Top 20 Food and Drug Cases, 2013 & Cases to Watch, 2014," *FDLI,* April 2014
- "Commonwealth Brands, Inc. et al. v. United States, et al.," *Top 20 Food and Drug Cases, 2009 & Cases to Watch 2010, FDLI* (2009).
- "FDA Tobacco Regulation: The Dog That Caught the Bus?" *Update, FDLI*, November/December 2009.
- "The Right Tool for the Job: Closing Hatch-Waxman Act Loopholes Requires Legislative Reform," *Update, FDLI*, March/April 2003.
- "Section 11 of the Best Pharmaceuticals for Children Act – A Prelude to Reform," *Update, FDLI*, March/April 2002.

NEWS & EVENTS

- 23 March 2022, 37th FDA Boot Camp--Drug and Biologic Labeling, Hosted by ACI
- 29 September 2021, FDA Boot Camp
- 22 May 2020, K&L Gates Advises Axonics on $150 Million Follow-On Public Offering
- 20 December 2019, K&L Gates Advises Beatty Marketing & Sales on Acquisition by Aspen Surgical Products
- 27 November 2019, K&L Gates Advises on Cross-Border $1.3 Billion Pending Tender Offer for Veloxis Pharmaceuticals
- 29 April 2019, K&L Gates Cross-Platform Team Advises LG Household & Healthcare Company in Acquisition Agreement with New Avon LLC
- 21 November 2018, K&L Gates Advises Axonics on $138 Million IPO
- 6 October 2017, K&L Gates Advises Ridgemont Equity Partners on Acquisition of Tech-Enabled Medical Products Distributor

AREAS OF FOCUS

- Food, Drugs, Medical Devices, and Cosmetics (FDA)

- Health Care and FDA
- Pharma and BioPharma Litigation

INDUSTRIES

- Digital Health
- Health Care Sector
- Life Sciences
- Pharmaceuticals, Biologics, and Medical Devices

REPRESENTATIVE EXPERIENCE

- Represented a personal care products manufacturer on responding to FDA inspectional observations and conducting cosmetic and drug product recalls. Worked with the company's internal quality professionals and external consultant to develop a plan for corrective and preventative actions in response to the FDA inspection.
- Provided counseling to specialty pharmaceutical company on numerous FDA regulatory, fraud/abuse compliance, and pharmaceutical pricing matters including: performing regulatory due diligence on proposed marketing arrangements and acquisitions, advising on VA and Medicaid Drug Rebate pricing issues, FDA regulated clinical trial matters, group purchasing organizational contracting issues, and country of origin labelling.
- Successfully petitioned CMS for a "narrow exception" allowing on behalf of a large pharmaceutical company for one of their drugs to be subject to a reduced Medicaid rebate.
- Advised providers and suppliers on pharmaceutical managed care, Medicare Part D, and Group Purchasing Organization agreements.
- Represented a pharmaceutical company in numerous regulatory matters including assistance with New Drug Application (NDA) submissions, counseling concerning clinical trial informed consent issues, licensing agreements concerning combination (drug/device) products, and FDA recall issues.
- Represented tobacco company on numerous Substantial Equivalence Reports, grandfather determinations, appeals of NSE Orders, and meetings with FDA's Center for Tobacco Products.