HOGAN & HARTSON

BRIAN R. MCCORMICK

Associate, Washington, D.C.

PHONE
+1.202.637.8859

FAX
+1.202.637.5910

brmccormick@hhlaw.com

Brian McCormick's practice focuses on the U.S. Food and Drug Administration's regulation of pharmaceuticals and biological products. Brian has particular experience with a wide variety of life cycle management issues, including those arising under the FDA Amendments Act, the Medicare Modernization Act, the Hatch Waxman Act, the Orphan Drug Act, and the Best Pharmaceuticals for Children Act. Brian has counseled clients on the approval pathways, marketing exclusivities, opportunities, and challenges presented by sections 505(b)(1), 505(b)(2), and 505(j) of the Food, Drug, and Cosmetic Act, as well as section 351 of the Public Health Service Act. He has worked with clients to structure pipeline and development programs, draft proposed labeling, maximize the benefit of intellectual property, and evaluate licensing and partnership opportunities. Brian also has worked with clients to prepare landmark citizen petitions and other submissions concerning the approval requirements for generic versions of narrow therapeutic range drugs, topical and other locally acting drugs, and drug-device combination products, among others. A number of these cases have culminated in high profile litigation against the government.

Brian also spends a significant amount of time counseling clients on issues concerning the advertising and promotion of pharmaceuticals and biological products. He has served as in-house counsel for a large biotechnology company, advising sales and marketing staff on a variety of promotional issues, including those arising under the Anti-Kickback Statute and the False Claims Act. Brian also has served as the legal or regulatory representative on six companies' promotional and non-promotional review committees, ranging from emerging companies with single products to larger companies with well-established product lines. Brian has conducted training programs for home office and field-based personnel for several clients.

Prior to attending law school, Brian worked in the U.S. Department of Health and Human Services as a program analyst in the Office of HIV/AIDS Policy. While in law school, Brian served on the editorial staff of the *American Criminal Law Review*.

Brian has presented on a wide variety of topics, including the Hatch Waxman Act and life cycle management, advertising and promotion issues, product liability and preemption,

PRACTICES/INDUSTRIES

Food, Drug, Medical Device, and Agriculture

Pharmaceutical and Biotechnology

Intellectual Property

Life Sciences

EDUCATION

J.D., *magna cum laude, Order of the Coif*, Georgetown University Law Center, 2002

M.H.S., Johns Hopkins University School of Public Health, 1999

B.A., *magna cum laude, Phi Beta Kappa*, Franklin & Marshall College, 1997

MEMBERSHIPS

Advisory Board, BNA Publication's *Pharmaceutical Law & Industry Report*

BAR ADMISSIONS

District of Columbia

and FDA's regulatory processes. In November 2008, Brian will co-chair the Bureau of National Affairs conference "Pharmaceutical Patent Law: A Prescription for Success in Challenging Times."

HOGAN & HARTSON PUBLICATIONS

"FDA Interprets Controversial 180-Day Exclusivity Forfeiture Provision." *Pharmaceutical and Biotechnology Update,* Hogan & Hartson LLP (01.29.2008)

"Court Upholds FDA Delay of Norvasc® Generic Approvals." *Pharmaceutical and Biotechnology Update,* Hogan & Hartson LLP (05.04.2007)

PUBLISHED WORKS

"Seizure Of Cosmetic Signals New Enforcement Trend." *Health Law360,* Portfolio Media, Inc. (02.22.2008)

PUBLISHED WORKS PRIOR TO JOINING HOGAN & HARTSON

2001

"Federal Food and Drug Act Violations," *38 Am. Crim. L. Rev. 819.*