Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?

John N. Joseph, David Deaton, Houman Ehsan, and Mark A. Bonanno

ABSTRACT: Off-label drug or medical device "use" is the practice of prescribing drugs or medical devices to patients for a purpose not included on the federally approved label. Off-label "marketing" is the practice of attempting to influence physicians to prescribe drugs or devices for off-label purposes. The federal Food and Drug Administration (FDA) maintains regulatory authority over the proper labeling of drugs and medical devices. Although not illegal, off-label use of certain drugs has led to controversy in recent years, especially in light of alleged behind-the-scenes marketing practices intended to increase off-label prescribing. Off-label marketing practices are prohibited and could result in criminal charges against a manufacturer, depending upon the circumstances. Yet a vast gray area exists for subtle marketing practices, such as circulating published medical studies about off-label uses to physicians. This article summarizes the legal and medical standards associated with off-label use and marketing of drugs, provides summaries of recent enforcement activities regarding off-label marketing, and explains the current federal regulatory issues surrounding off-label marketing practices. The authors provide practical pointers on regulatory compliance and the risks associated with fraud and abuse laws for drug companies and practitioners.

CITATION: John N. Joseph, David Deaton, Houman Ehsan, and Mark A. Bonanno, *Enforcement Related to Off-Label Marketing and Use of Drugs and Devices: Where Have We Been and Where Are We Going?*, J. Health & Life Sci. L., January 2009, at 73.

The authors' biographical statements appear on the following page.

John N. Joseph, Esquire, former criminal prosecutor and Deputy Chief of the Civil Division at the U.S. Attorney's Office in the Eastern District of Pennsylvania, is a partner in the Philadelphia-based firm Post & Schell, PC, where he is part of a national practice in white collar defense, internal investigations, and corporate compliance. Mr. Joseph focuses on healthcare fraud issues and has lectured on white collar crime, the False Claims Act, and trial advocacy at the Department of Justice's National Advocacy Center. Mr. Joseph serves on the American Health Lawyers Association Fraud and Abuse Enforcement Panel. Contact him via email at jjoseph@postschell.com.

David Deaton, Esquire, is a partner in the Los Angeles office of O'Melveny & Myers LLP, and a member of the firm's Health Care and Life Sciences practice. Mr. Deaton's practice principally focuses on complex regulatory and business matters involving various healthcare organizations. Contact him via email at ddeaton@omm.com.

Houman Ehsan, Esquire, J.D., M.D., M.B.A., is counsel in the Los Angeles office of O'Melveny & Myers LLP, and a member of the firm's Health Care and Life Sciences practice and Class Actions, Mass Torts, and Aggregated Litigation practice. He focuses on analyzing legal and factual issues involving complex technical medical or scientific components in healthcare litigation and regulatory settings. Contact him via email at hehsan@omm.com.

Mark A. Bonanno, Esquire, J.D., M.P.H., is a Portland, Oregon-based attorney in private practice. The Law Offices of Mark A. Bonanno, LLC provides outside general counsel services for established and emerging businesses, and specializes in problem-solving and regulatory guidance for healthcare companies and individual healthcare professionals. Contact him via email at mab@healthlawoffice.com.