Bloomberg Law®

bloombergbna.com



# INSIGHT: California v. AbbVie—Potential Limits in the Marketing of High-Risk Drugs



By Maria C. Nunez, Ashley N. Mays-Williams, Ph.D., and Julia M. Kolibachuk

On Sept. 18, 2018, the State of California (henceforth, referred to as the ''State'') sued AbbVie Inc. (''AbbVie'') and 25 undisclosed health-care providers (collectively, ''Defendants'') for allegedly violating California's Insurance Frauds Prevention Act. (D.I. 1 (C.A. RG18893169), Complaint.) The State's complaint supersedes an initial complaint filed by Lazaro Suarez, a registered nurse whose services were contracted by AbbVie from approximately March 2013 to October 2014 as part of an alleged kickback scheme. (*Id.* at paras. 11, 22-30.)

## I. Risks of AbbVie's Humira

Humira is a trade name for the monoclonal antibody adalimumab, an anti-inflammatory drug currently indicated for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, pediatric Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis. (*Id.* at paras. 44, 47.) Humira acts by binding tumor necrosis factor alpha (''TNF-α''), a signaling protein, and thereby reducing the body's inflammatory response. Humira sales in 2017 totaled over $12 billion. (*Id.* at para. 44.) The State's complaint alleges that from 2013 to August 2018, private insurers paid above $1.29 billion for more than 274,000 Humira claims from California-insured patients alone. (*Id.* at para. 45.)

The Humira label indicates use of the drug can be accompanied by serious side effects. Food and Drug Administration boxed warnings on the Humira label describe side effects as including ''serious infections that may lead to hospitalization or death,'' and also state that ''[l]ymphoma and other malignancies, some fatal, have been reported.'' (*Id.* at para. 46.)

## II. Allegations Directed at AbbVie's Marketing Strategies Concerning Humira

The *California v. AbbVie* litigation centers on allegedly fraudulent activities committed by AbbVie in an effort to bolster Humira sales. The complaint states that AbbVie offered ''classic kickbacks'' to medical providers, including ''cash, meals, drinks, gifts, trips, and patient referrals.'' (*Id.* at para. 1.) Beyond these, the State alleges that AbbVie engaged in a purported ''sophisticated'' kickback scheme comprising ''free and valuable professional goods and services to physicians to induce and reward Humira prescriptions.'' (*Id.*) For example, AbbVie is alleged to have provided ''expensive and sophisticated proprietary software and technology'' and assistance in the promotion of the provider's medical practice at no cost to the provider. (*Id.* at para. 98.)

Notably, the State asserts that AbbVie's provision of registered nurse ''Ambassadors'' to patients in their homes, to ''provide patient care, pharmacy and insurance authorization assistance, open enrollment resources, paperwork help, [and] advice on insurance products,'' was also a form of kickbacks because these benefits were provided only to physicians who prescribed Humira as opposed to other forms of treatment. (*Id.* at paras. 2, 98, 102, 113, 117, 126.) According to the State, these services are typically provided by nurses and staff hired by physicians at substantial cost. (*Id.* at para. 48.) Further, the State alleges that registered nurses acting as AbbVie Ambassadors provided pa-

tients with one-sided information, ''deflecting'' patients' questions about Humira's side effects and instead focusing on potential benefits and how they could help patients obtain the drug at discounted rates. (*Id.* at paras. 2, 28.) According to the complaint, AbbVie also employed health-care providers to promote the use of Humira at higher dosages and frequency than those indicated on the Humira label (''off-label escalated dosing''). (*Id.* at para. 148.) Through such conduct, the State alleges that AbbVie interfered in doctor-patient relationships and increased insurance spending on Humira prescriptions. (*Id.* at paras. 4, 76.)

These allegations are said to be reminiscent of earlier claims against Abbott Laboratories Inc. (''Abbott''), AbbVie's predecessor. In 2012, before AbbVie was formed from Abbott, Abbott agreed to pay $1.5 billion to resolve criminal and civil liability for unlawful promotion of the epilepsy drug Depakote for off-label use. *See* Press Release, Dep't of Justice, Office of Pub. Affairs, Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote (May 7, 2012). Abbott pled guilty to misbranding Depakote because it promoted use of the drug for agitation and aggression in elderly dementia patients and schizophrenia when the FDA had only approved Depakote for epileptic seizures, bipolar mania, and the prevention of migraines. *Id.* Abbott's alleged off-label promotion strategy involved marketing Depakote for the treatment of schizophrenia even after studies evaluating the use of Depakote to treat schizophrenia failed. *Id.* Not only did Abbott allegedly wait almost two years to notify its sales force about the study results, but it also waited another two years to publish those same results for the public's benefit. *Id.*

In the current action, the State not only seeks equitable remedies, including temporary and permanent injunctive relief, but also three times the amount of any Humira-related insurance claims for compensation ultimately found fraudulent and $10,000 in civil penalties for any such fraudulent claim. (D.I. 1 (C.A. RG18893169), Complaint at Section VIII, paras. 1-4.) The State also seeks attorneys' fees, expenses, and the cost of litigation. (*Id.* at Section VIII, para. 5.)

## III. Potential Limits on Marketing Practices Involving High-Risk Drug Products

Through litigation, the Department of Justice has previously challenged various promotional efforts for drug products, including promotion of off-label uses, and these actions have been well publicized due to the large fines often associated with settlement of such allegations. The current *California v. AbbVie* litigation makes clear, however, that in addition to promotion of off-label uses, a marketing scheme that allegedly i) uses financial incentives to increase dosages or greater frequency of administration of pharmaceutical products, ii) interferes with doctor-patient relationships, and iii) induces additional private insurance claims can also be subject to claims of liability under state laws designed to prevent insurance fraud. Some states allow for whistleblowers to bring cases against any person or company that defrauds private insurance companies and to share in a portion of the government's recovery. These incentives to whistleblowers emphasize the need for truthful marketing campaigns free of attempts to mislead the FDA, doctors, and patients, particularly when high-risk drugs are the subject of such campaigns.

## Author Information

Maria C. Nunez is an associate in the Litigation practice of Paul Hastings. Her practice focuses on intellectual property, including complex patent litigation in the fields of pharmaceuticals and biotechnology. In addition to her J.D., Ms. Nunez earned her Master of Public Health from the Johns Hopkins Bloomberg School of Public Health.

Ashley N. Mays-Williams, Ph.D. is an associate in the Litigation practice of Paul Hastings. Her practice focuses on intellectual property, including complex patent litigation in the fields of pharmaceuticals and biotechnology. In addition to her J.D., Dr. Mays-Williams earned her Ph.D. in Medical and Molecular Genetics from King's College London.

Julia M. Kolibachuk is an associate in the Litigation practice of Paul Hastings. Her practice focuses on complex patent litigation in the pharmaceutical and biotechnology fields. Ms. Kolibachuk earned a B.S. in Biological Sciences with Honors from Stanford University, and conducted molecular biology research at the University of California, San Francisco, for two years prior to law school.