AMERICAN HEALTH LAWYERS ASSOCIATION

PRACTICE GROUP *email alert*

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**"Off-Label" Marketing and Use of Drugs Regulated by the FDA**
By Mark Bonanno*

On March 18, 2008, the U.S. Department of Justice (DOJ) announced information about a criminal indictment for wire fraud and Food, Drug, and Cosmetic Act (FDCA) violations against the former CEO of a drug company. The indictment highlights the legal questions about "off-label" marketing and use of drugs regulated by the Food and Drug Administration (FDA).

The drug company marketed and sold an FDA-approved drug to treat two rare diseases. According to the indictment, however, the drug company also marketed and sold the same drug to treat another disease known as idiopathic pulmonary fibrosis (IPF). Treating IPF with the drug was not approved by the FDA. In other words, the drug was being marketed and sold for off-label use.

Off-label use of a drug (versus marketing of a drug) generally is not considered illegal if the intent of the use is the practice of medicine. American Medical Association policy has noted that a physician may lawfully use an FDA-approved drug for an unlabeled indication when the use is based upon sound medical opinion and scientific evidence. But, the FDA does not permit drug companies to market drugs for non-approved purposes. Notably, the FDA does permit a drug manufacturer to disseminate information about scientific studies of a drug for off-label purposes, but only if certain regulatory conditions are met. The focus of the indictment in this case seemed to be related to allegations that a vast majority of the drug company's sales were for the off-label use of treating IPF. The cost of the drug for one patient for one year was $50,000.

The government alleged that even though early studies of the drug to treat IPF had failed, the former CEO proceeded with an extremely successful marketing campaign that promoted the drug as a safe and effective treatment for IPF. Sales of the drug from 2000 through 2003 apparently increased from $11 million to $141 million. The government

contended that such a promotion of the drug was a scheme to defraud doctors and patients and led to a two-count indictment against the former CEO for wire fraud and a violation of the FDCA for misbranding a drug. If proven, the potential imprisonment penalties are 20 years on the wire fraud charge and 3 years on the FDCA charge.

In 2006, the company settled criminal and civil charges in connection with the alleged illegal promotion of the drug, and entered into a five-year Corporate Integrity Agreement (CIA) with the Office of Inspector General. Such a settlement would not have included findings of liability. The CIA required continuation of an internal compliance program as well as an external review of the company's marketing activities.

Copies of the DOJ press release, indictment, and the drug company CIA are posted in the Fraud and Abuse, Self-Referrals, and False Claims Practice Corner.

**We would like to thank Mark Bonanno (Law Offices of Mark A. Bonanno LLC, Portland, OR) of the Enforcement Subcommittee for providing this email alert.*

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Member benefit educational opportunity:
Teleconference on practical strategies for resolving False Claims Act cases (April 29, 2008).



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