

MEDIA MENTION

Bert Rein Comments on FDA Marketing Rules for Prescription Drugs

The Wall Street Journal

December 7, 2012

Wiley Rein founding partner Bert W. Rein was quoted by *The Wall Street Journal* in a December 5 story about a legal challenge to the Food and Drug Administration's ban on the marketing of prescription drugs for unapproved uses.

The Ninth Circuit U.S. Court of Appeals in San Francisco is hearing an appeal this week of a biotechnology executive's 2009 wire fraud conviction, which stemmed from a news release that the government contends made false statements about a drug's benefits. The executive is seeking to overturn his conviction on the grounds that the news release "expressed a scientific view" that is protected as free speech under the First Amendment, *The Journal* reported.

The case is the second legal challenge this week to the FDA's off-label marketing restrictions, according to the article. The Second Circuit Court of Appeals in New York on December 3 vacated, on First Amendment grounds, the 2008 conviction of a sales representative who had marketed a drug for unapproved uses. Both cases threaten the government's ability to extract billion-dollar settlements from companies that engage in off-label marketing, *The Journal* reported.

"It is important to the FDA to preserve the notion that you can't sell a medicine for an unapproved purpose," Mr. Rein, who has represented an opponent of FDA marketing rules, told *The Journal*. "That agency is so vested in its regulatory scheme that they will fight."

Mr. Rein has been recognized by *Legal Times* as Washington's "Leading Food and Drug Lawyer."

Related Professionals

Bert W. Rein
Founder
202.719.7080
brein@wiley.law

Practice Areas

Food & Drug
Issues and Appeals