

# Client Alert

Special Matters & Government Investigations Practice Group  
FDA & Life Sciences Practice Group

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## Settle or Fight FDA/DOJ Off-Label Use Allegations? WSJ Editorial Looks at Vascular Solutions Trial Win and Asks What's Next?

In an editorial this weekend entitled “No Justice for Business,” The Wall Street Journal hailed a recent trial win by medical device maker Vascular Solutions, Inc. (VSI) as a “victory for common sense and the First Amendment” as it “will now force the FDA to reconsider the way it deals with how companies market their products.” The editorial also raises questions about how pharmaceutical and medical device companies might face future inquiries by the FDA and DOJ on the issue of off-label marketing.

King & Spalding's Michael Pauzé, John Richter, and Robert Hur, all former DOJ prosecutors, defended VSI at trial, which the WSJ characterized as an attempt by the Justice Department to criminalize “honest behavior,” namely, providing wholly truthful and non-misleading information about the unapproved use of a medical device. Also supporting the defense of VSI were Jeff Bucholtz and others from King & Spalding's National Appellate practice and the firm's FDA & Life Sciences practice group.

The matter had begun as a whistle-blower case that led to criminal indictments of the company and its CEO. As the WSJ wrote, the “company wasn't spreading false information—off-label uses often work as therapies” and yet “FDA has taken the position that companies cannot share information about products for uses it hasn't authorized.” The piece went on to describe what it views as the FDA's and DOJ's strategy to force “companies into fines and settlements without ever going to trial. Threaten a CEO with trumped up criminal charges, then watch the company settle to avoid the expense and reputational damage of a long legal defense.”

The jury returned a verdict of acquittal on all counts.

For King & Spalding, it was a hard-fought victory on behalf of Vascular Solutions that brought together the firm's Special Matters & Government Investigations, National Appellate and FDA & Life Sciences teams.

Click [here](#) to view the full editorial. (A subscription to the WSJ is required.)

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