

FEATURED ARTICLE

To Promote or Not to Promote? The Enforceability of FDA's Off-Label Marketing Restrictions Following *Amarin*

Matthew T. Newcomer and Yune T. Do

What is the issue? Federal courts have held that the First Amendment prevents FDA from prohibiting pharmaceutical manufacturers from truthful non-misleading promotional speech on off-label product use. Most recently, a federal district court in *Amarin Pharma v. FDA* prevented the government from bringing criminal charges based on such speech. Does *Amarin* mark the beginning of the end for FDA's off-label marketing prohibitions or is it a fact-specific holding with little impact?

What is at stake? What is at stake is the ability of pharmaceutical companies and agents to freely engage physicians in truthful non-misleading promotional discussions about the benefits of drugs used to treat off-label conditions. If the *Amarin* decision is adopted widely, the improved flow of information could foster improved medical decision-making.

What should attorneys do? Significant practical and legal considerations make it likely the pharmaceutical industry will continue to observe FDA's traditional restrictions on off-label promotion. Therefore, attorneys should consider the risks and benefits of following *Amarin's* lead by pre-clearing off-label promotional content with the courts.

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Author biographies appear on the next page.

Matthew T. Newcomer is a Principal with Post & Schell, P.C.'s Internal Investigations & White Collar Defense Group. Mr. Newcomer conducts internal investigations and counsels corporations and individuals facing civil and criminal investigation, including matters involving off-label sales and marketing practices, the Anti-Kickback Statute, the Responsible Corporate Officer or Park doctrine, the federal False Claims Act, and federal and state racketeering statutes. Contact him via email at mnewcomer@postschell.com.

Yune T. Do is an Associate in Post & Schell's Internal Investigations & White Collar Defense Group. Her practice includes conducting internal investigations and defending clients facing criminal and civil investigations relating to off-label marketing. Contact her via email at ydo@postschell.com.

Newcomer and Do: Off-Label Marketing

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