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THE CHANGING LANDSCAPE OF OFF-LABEL PRESCRIPTION DRUG MARKETING

Two recent federal court decisions have changed the landscape of off-label prescription drug marketing by pharmaceutical companies. While providers may prescribe U.S. Food and Drug Administration ("FDA")-approved drugs for off-label uses, pharmaceutical companies and their representatives are prohibited from promoting the use of FDA-approved drugs off-label as the Federal Drug and Cosmetic Act ("FDCA") prohibits and criminalizes the misbranding of drugs. As a result, providers should carefully evaluate their interactions with manufacturers concerning off-label use of pharmaceuticals. FDA approval for particular indications and sub-populations remains the gold standard, and providers should give pause to any promotion of off-label uses by pharmaceutical companies until those uses have been proven to be safe and effective. Below is a brief summary of both cases and some practical takeaways for providers as they navigate their relationships with pharmaceutical companies.

***UNITED STATES V. CARONIA*, 703 F.3D 149 (2D CIR. N.Y. 2012)**

For years, the federal government has aggressively brought charges against pharmaceutical manufacturers and their representatives for the off-label promotion of medications. However, in December 2012, a federal court overturned a former pharmaceutical representative's criminal conviction under the FDCA for promoting off-label uses of an FDA-approved drug, stating that the conviction violated his First Amendment right to free speech. The defendant sales representative was audio recorded promoting off-label uses of an FDA-drug for unapproved indications and sub-populations. The federal government subsequently charged the pharmaceutical company and the sales representative with two counts of misbranding and conspiracy under the FDCA. On appeal, the court found that the promotion of off-label uses that is neither untruthful nor misleading does not violate the FDCA. While this decision leaves the door open for prosecution under the FDCA for untruthful or misleading off-label promotion, the federal government can no longer "prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."

***KAISER FOUNDATION HEALTH PLAN, INC. V. PFIZER, INC.*, 712 F.3D 21 (1ST CIR. MASS. 2013)**

In April 2013, a federal court affirmed a $142 million verdict against the drug manufacturer Pfizer and in favor of a large health plan for the systematic and fraudulent marketing of off-label uses that caused the health plan millions of dollars in excess costs. This damage award was in addition to $430 million in civil and criminal fines that the federal government had already levied against Pfizer for its off-label promotion.

The court found that Pfizer violated federal and state laws in its marketing of off-label uses of Neurontin. Pfizer's fraudulent marketing tactics included direct marketing to physicians that misrepresented the effectiveness of the off-label uses, sponsoring and providing misleading information in continuing medical education and supplements to physicians, suppressing negative information about the drug, publishing information in medical journals about the effectiveness of off-label uses and targeting payors for inclusion on formularies to influence prescribing decisions. The court found that the health plan and its employees had directly relied on misrepresentations made by Pfizer and that Pfizer's fraudulent marketing caused physicians to issue more prescriptions of the drug than they otherwise would have.

PRACTICAL TAKEAWAYS

While the *Caronia* decision cleared the way for pharmaceutical companies to provide truthful, non-misleading information regarding effective off-label uses, the *Pfizer* case illustrates that off-label promotion by pharmaceutical manufacturers and their representatives is not always reliable and can affect the prescribing habits of providers. In light of these recent court decisions, providers should consider doing the following:

- Developing policies to limit pharmaceutical representatives from instructing physicians about off-label uses of pharmaceutical drugs;
- Monitoring and reviewing the off-label prescribing practices of affiliated providers;
- Implementing heightened monitoring for off-label prescribing for drugs that carry serious safety concerns or that have black box labeling;
- Reviewing and revising health plan formularies to restrict off-label prescribing, unless medically necessary and generally accepted by the medical field;

- Ensuring that patient education materials and websites describe only FDA-approved uses of pharmaceutical drugs;
- Encouraging providers to conduct independent research or meta-analysis concerning off-label uses or to document their own clinical findings to assess the effectiveness of off-label uses; and
- Educating physicians to make treatment decisions based on their own clinical experience or literature review and not in reliance on pharmaceutical promotion of off-label uses.

If you have any questions about off-label use, please contact:

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Please note that this discussion is focused on off-label promotion related to the use of pharmaceuticals and not medical devices (products), which are similarly subject to off-label use concerns.

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