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Client Alert

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Half-truths, Off-label Indications and the Specter of RICO Liability

"Beware of the half-truth. You may have gotten hold of the wrong half."
– Anonymous

Pharmaceutical companies cannot advertise drugs for uses other than those approved by the Food and Drug Administration (FDA) but can provide information upon an unsolicited request related to "off-label" uses in certain situations. Off-label indications raise a host of ethical and legal concerns for hospitals and medical professionals. Courts have held that evidence showing that a drug was prescribed by a physician for uses not specifically approved by the FDA can be introduced for purposes of showing that the physician departed from the standard of care in medical malpractice actions, and neglecting to inform a patient that a drug is being prescribed for an off-label use can expose the prescribing doctor to liability for failure to obtain informed consent.

Recently, however, the stakes for pharmaceutical companies in providing information related to off-label indications were raised still further. Earlier this year, a federal court in Massachusetts held that drug companies may be exposed to liability under the Racketeer Influenced and Corrupt Organizations Act (RICO) when they neglect to fully disclose the potential negative effects or ineffectiveness of off-label indications. The decision in *In re Neurontin Marketing and Sales Practices Litigation*, Civil Action No. 04-CV-10981-PBS (D. Mass. Jan. 8, 2010) is significant, because defendants found liable for violating RICO can face massive liability exposure—three times the *actual* harm suffered by claimants as a consequence of their non-disclosure.

In the *Neurontin* decision, consumers and third-party payors brought a claim under RICO alleging that Warner-Lambert Co. and Pfizer, Inc., marketed Neurontin for a variety of off-label indications, including for treatment of bipolar disorder, neuropathic and nociceptive pain, and migraines, and for dosages above the 1,800mg. per day dosage approved by the FDA. The drug makers responded to third-party payor and physician inquiries about Neurontin by summarizing positive studies touting the benefits of the drug for these uses and dosages, but neglected to disclose studies showing the drug's ineffectiveness, *vis-à-vis* a placebo to treat certain conditions, negative side effects of the drug or the drug's lack of improved efficacy at higher dosages. The plaintiffs alleged that these disclosures increased the sales of the drug in circumstances where the drug was ineffective or where cheaper and more optimal alternatives existed to treat the conditions for which it was prescribed.

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The pharmaceutical companies argued that they were under no duty to disclose these negative studies in response to inquiries and, thus, that their disclosures were not "fraudulent"—a prerequisite for finding that they engaged in a pattern of mail and wire fraud in violation of RICO. The *Neurontin* court disagreed. Although dismissing certain plaintiffs' RICO claims based on a lack of proof of causation (i.e., a showing that the alleged instances of mail and wire fraud actually caused physicians to prescribe the drug), the court nevertheless held that the suppression of negative studies by the drug makers could sustain RICO liability. It reasoned that "the *locus classicus* of fraud is a seller's affirmative false statement or a half truth, i.e., a statement that is literally true but is made misleading by a significant omission." Because at least one plaintiff had relied on the materially incomplete disclosures made by the drug companies respecting off-label indications, the court ruled that it would be permitted to take its RICO claims to trial, exposing the defendants to the specter of treble damages under the statute.

At this time, the full implications of the *Neurontin* court's decision remain murky. Conceivably, the court's holding opens the door to liability, not only to drug makers, but also to other health care providers aware of negative studies regarding off-label indications who fail to disclose those studies to consumers and third-party payors. Until those issues are resolved, however, healthcare providers and drug companies should be mindful of the courts' willingness to accept the truth of the old proverb, "A half truth is a whole lie."