



## Client Alert

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## Merck Settles Anti-Kickback and Drug Rebate Allegations with Federal and State Governments

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Merck agreed to settle two whistleblower lawsuits under the False Claims Act that alleged best price reporting violations and illegal kickbacks to doctors and hospitals. With interest included, the total settlement amount of the lawsuits was \$671 million. In addition, Merck agreed to enter into a Corporate Integrity Agreement with the Office of Inspector General ("OIG").

**Background:** The acts in question spanned a period from 1996-2006. A former district manager for Merck filed a whistleblower suit in Philadelphia alleging that Merck, from 1998-2006, violated the Medicaid Rebate Statute by failing to report the "best prices" for three of its products (Zocor, Mevacor and Vioxx). Under the Rebate Statute, a company is required to report their lowest prices and other pricing information to the government to ensure that the government receives the same discounts and concessions the company gives to others.

The whistleblower alleged that the company offered significant discounts to hospitals for the products in return for the hospitals using large quantities of the products instead of rival brands. The suit also alleged that the company failed to report these discounted prices to the government in violation of the Medicaid Rebate Statute.

The same whistleblower alleged that Merck, from 1997-2001, had several programs in place for its sales representatives to induce doctors to prescribe its products. The programs allegedly involved excess fees paid to doctors for training, market research, and general consulting. Merck agreed to pay \$399 million plus interest to settle the Medicaid Rebate and anti-kickback allegations. The whistleblower was awarded \$68 million for bringing the suit.

A separate suit filed by another whistleblower (who was a doctor) alleged that Merck, from 1996-2001, provided hospitals with significantly reduced prices for prescription Pepcid in exchange for the hospital using the product

as its primary heartburn medicine rather than a rival product. Allegedly, Merck provided these discounts so that persons discharged from the hospital would continue to use its product. The suit asserted that the company failed to report the discounted prices to the government. Merck agreed to pay \$250 million plus interest to settle the allegations, and the whistleblower will receive a percentage of the settlement amount.

The federal government will receive approximately \$360 million from the two settlements and forty-nine states (Arizona did not participate in the settlement) and the District of Columbia will divide approximately \$290 million. In addition to the payments and the Corporate Integrity Agreement with the OIG, the settlement requires Merck to enter into settlement agreements with various states.

For over seven years Merck expended significant company resources responding to the allegations. The first whistleblower complaint was filed in December 2000. The whistleblower met with federal and various state officials to coordinate their investigations. In response to the suit, Merck turned over more than 1.5 million pages of documents. As outlined above, Merck not only faced scrutiny from the federal government, but it faced the possibility of responding to complaints filed by individual states. (We have outlined states' incentives to enact statutes similar to the False Claims Act in previous bulletins.)

**Practice Highlight:** The settlement of these cases underscores the importance of drafting, implementing, and ensuring compliance with standard operating procedures governing a company's marketing and sales practices. A company must also ensure that any marketing programs are disclosed and understood by all affected teams at the company and that the company has adequate auditing programs to ensure compliance with its SOPs. (Merck said it believed that it was complying with the Medicaid rules at the time.) Finally, companies must establish a system whereby employees with concerns regarding company practices may be heard and such concerns investigated and documented.

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