

## FOR IMMEDIATE RELEASE

Cincinnati, Ohio

October 30, 2012

Morgan Verkamp LLC, a Cincinnati law firm which represents *qui tam* whistleblowers under federal and state False Claims Acts, represents Mr. Donald Galmines, a former Novartis marketing representative whose responsibilities included the marketing of the topical cream Elidel<sup>®</sup>, which has been approved by the FDA for use on patients more than two years old who suffer from eczema and whose condition is not well-controlled by preferred, “first-line” treatments.

Novartis has contracted to pay the State of Texas \$19,900,000 to resolve allegations that Novartis “misrepresented and concealed information about the safety, efficacy and appropriate use of Elidel<sup>®</sup> and improperly induced health care providers to prescribe Elidel<sup>®</sup>, thereby committing unlawful acts in Texas.”

The settlement resolves, with respect to Texas, allegations first brought by Mr. Galmines in the United States District Court for the Eastern District of Pennsylvania, in 2006. The case is *United States, et al. ex rel. Donald Galmines v. Novartis Pharmaceutical Corporation*, Civil Action No. 2:06-cv-03213-GP, and it remains pending except as to Texas. The suit alleges that Novartis engaged in a practice known as “off-label marketing” by requiring its sales representatives to induce doctors to prescribe Elidel<sup>®</sup> for uses not approved—and specifically rejected—by the Food and Drug Administration.

The primary off-label use at issue was for treatment of eczema, or “atopic dermatitis,” in children younger than two years of age. Elidel<sup>®</sup> was not shown by Novartis to be safe and effective for such uses. Indeed, in 2005, the FDA required Novartis to put a “Black Box Warning” on Elidel<sup>®</sup> packaging, warning physicians and consumers that certain cancers in infants were associated with the use of Elidel<sup>®</sup>. Mr. Galmines’s Pennsylvania complaint also alleges that Novartis required its sales force to market Elidel<sup>®</sup> for numerous conditions other than eczema, and that it paid physicians kickbacks to encourage them to do so.

Under the False Claims Act, a whistleblower is empowered to bring a civil action alleging that a supplier such as Novartis caused the submission of false claims for payment to federal health insurance programs such as Medicare, and also to the federal-state program, Medicaid. The U.S. Department of Justice elected not to intervene in the Pennsylvania complaint filed by Mr. Galmines, and,

pursuant to rights guaranteed him by the False Claims Act, Mr. Galmines is proceeding with that case on behalf of the United States and several states, including California, Massachusetts, Virginia, Illinois, and Michigan. The Pennsylvania court recently issued an order on motion to dismiss directing Relator to amend the complaint within 30 days in order to proceed, and Relator will file the requested amendment.

Mr. Galmines's complaint initially included claims on behalf of the State of Texas. Those claims were voluntarily dismissed, and subsequent events led to the settlement announced today. That settlement provides for payment of attorney fees to the State of Texas and counsel for Mr. Galmines, as well as for a recovery of a share of the settlement to Mr. Galmines pursuant to the Texas Medicaid Fraud Prevention Act, which provides that a whistleblower such as Mr. Galmines is paid between 15% and 25% of such a settlement.

The State of Texas is represented in the case by Raymond C. Winter, Chief of the Texas Attorney General's Civil Medicaid Fraud Division, and Assistant Attorneys General Cynthia O'Keefe and Chari Kelly, also of the Civil Medicaid Fraud Division. According to Frederick Morgan of Morgan Verkamp, "The Texas Attorney General's Office has long been a national leader in the effective use of the state's Medicaid Fraud Prevention Act to investigate and resolve allegations brought by whistleblowers, especially those involving false claims for payment caused by illegal marketing of pharmaceutical companies. The leadership role taken by Texas in addressing the marketing of Elidel<sup>®</sup>, which contains a powerful carcinogen, for use on the skin of infants demonstrates once again that the Lone Star State takes a back seat to no one when it comes to aggressively fighting Medicaid fraud."

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