

NEWS RELEASE
MONTANA DEPARTMENT OF JUSTICE
ATTORNEY GENERAL TIM FOX

FOR IMMEDIATE RELEASE | January 17, 2014
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**Attorney General Fox Announces Multistate Settlement with
CareFusion Corporation**

HELENA -- Attorney General Tim Fox announced today that Montana has joined with other states and the federal government in a global settlement with CareFusion, a manufacturer of medical and surgical supplies and medical devices, to resolve civil allegations of unlawful marketing practices and the payment of kickbacks aimed at promoting sales of CareFusion's surgical preparation solution, Chloraprep.

Under the terms of the civil settlement, CareFusion will pay \$40.1 million to the states and the federal government. The settlement resolves a *qui tam*, or whistleblower, lawsuit filed in the United States District Court for the District of Kansas, under the provisions of the federal False Claims Act and analogous state False Claims statutes.

CareFusion, a corporation spun off from Cardinal Health in 2009, allegedly promoted and marketed Chloraprep for uses that were not approved by the Food and Drug Administration (FDA) some of which were not medically accepted indications. Once the FDA approves a surgical solution such as Chloraprep as safe and effective, its manufacturer cannot market or promote it for an "off-label" use, i.e., any use not specified in the FDA-approved product label.

"Whistleblower settlements like this are important because they seek to hold companies accountable for their allegedly improper conduct while also distributing funds back to public programming," said Attorney General Tim Fox. "These types of lawsuits are an important tool in the ongoing fight against health care fraud and abuse, and I'm pleased that Montana will receive a share of the CareFusion settlement."

The net portion of the settlement available for Montana's use is \$15,359.59. These funds will go to the Montana Department of Public Health and Human Services, which administers the Medicaid program in Montana.

Chloraprep was approved by the FDA for specific inpatient hospital procedures, including the preparation of a patient's skin prior to surgery or injection, but the FDA explicitly rejected its use for intravenous preparation and suture care. The lawsuit alleges that during the period between September 1, 2009 and August 31, 2011, CareFusion promoted Chloraprep for use with intravenous preparation and suture care, which went beyond the FDA-approved label uses for Chloraprep. CareFusion also allegedly made and disseminated unsubstantiated representations about the use of Chloraprep solutions during the same time period. The states further contend that during the course of several

months in 2008, CareFusion's predecessor corporation entered into agreements, as to which CareFusion assumed legal and financial responsibility, for the payments of monies to an entity known as Health Care Concepts, Inc. (HCC). The payments were allegedly made in order to conceal kickbacks to the physician-owner of HCC, for the purpose of promoting and inducing providers to use Chloraprep, in violation of various federal and state anti-kickback statutes.

CareFusion's alleged unlawful conduct caused false and/or fraudulent claims to be submitted to or cause purchases by government funded health care programs, including state Medicaid programs.

Thanks an amendment to the Montana False Claims Act requested in the 2013 Legislature by Attorney General Tim Fox and sponsored by Representative Cary Smith (HD 55), the Federal government now allows Montana to keep a greater share of damage awards and settlements in this and similar fraud cases.

A team from the National Association of Medicaid Fraud Control Units worked closely with the federal government on the investigation and conducted the settlement negotiations with CareFusion on behalf of the states.

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