

Date: July 12, 2016

To: All Providers

From: Ronald E. Voorhees, MD, MPH Medical Director, DDSD

Alert - Possible Contamination Do Not Use Liquid Docusate Products

CDC has issued a recommendation that liquid docusate products should not be used by any person due to potential contamination of these products. Docusate is commonly used as a stool softener and is sometimes used as a cerumen removal aid.

We recommend that caregivers check labels on stool softeners. Liquid products labeled as containing docusate salts or dioctyl sulfosuccinate are advised not to be used - if an oral liquid docusate stool softener is medically necessary, CDC recommends that alternative medicines should be used. Please consult with an individual's physician regarding an alternative treatment.

We will send updates as available. I have attached the CDC recommendations and investigation summary below.

CDC Recommendations (Emphasis added)

CDC continues to work with FDA, health departments and multiple healthcare facilities to investigate a multi-state outbreak of infections caused by *Burkholderia cepacia* complex (also known as "*B. cepacia* complex"). At this time, CDC continues to recommend that clinicians not use any liquid docusate product as a stool softener or for any other medical purpose. This recommendation is now expanded to all patient populations. If an oral liquid docusate stool softener is medically necessary, alternative medicines should be used.

CDC urges healthcare providers and laboratories to remain on alert for infections caused by *B. cepacia* complex occurring among non-cystic fibrosis (CF) patients and should inform infection prevention staff immediately when these infections are identified. In addition, although infections caused by *B. cepacia* complex are known to occur among patients with CF, any clusters of such infections should be reported. Cases and clusters should be reported to state or local public health authorities.

Facilities that identify infections caused by *B. cepacia* complex among non-CF patients or clusters of these infections among CF patients should sequester and save all docusate products used in the facility.



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Investigation Update

To date, 47 *B. cepacia* complex cases have been confirmed by molecular typing to match one of two outbreak strain types identified from healthcare facilities in five states. Reports of possible cases from additional states are currently being investigated. CDC has confirmed that two samples of unused oral liquid docusate product received from one of the affected hospitals have tested positive for *B. cepacia* complex. Further testing is being conducted to determine if bacteria from these samples match the outbreak strains. FDA is currently testing multiple liquid docusate products that are epidemiologically linked to reported *B. cepacia* complex cases. To date, CDC has confirmed one product as having *B. cepacia* complex growth; however, because of epidemiologic links, CDC is concerned about potential contamination of multiple liquid docusate products, pending FDA's ongoing investigation of shared ingredients in the products in question.

CDC will provide an update to this announcement by July 14, 2016. Please direct questions to haioutbreak@cdc.gov. Members of the media should contact the CDC Media Office at media@cdc.gov.