# Classified Ads



# Industry Spotlight

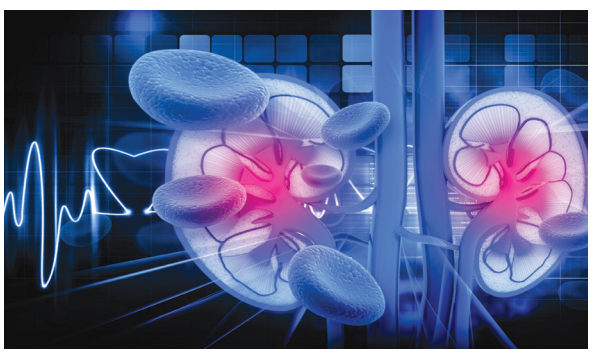
## Dialysate Concentrate Recalled

In July 2015, Fresenius issued a voluntary recall of more than 1.8 million 6.4-L bottles of NaturaLyte Liquid Bicarbonate Concentrate (see FDA website for details about the recalled units). The concentrate is formulated for use with a three-stream hemodialysis machine that is calibrated for acid and bicarbonate concentrates, the FDA noted.

NaturaLyte is also making news on some legal websites for a class-action suit against the manufacturer, alleging that the product, along with a different Fresenius dialysate product called GranuFlo, contributed to harmful and/or fatal side effects such as cardiac arrhythmia and low blood pressure. On July 1, 2015, the latest case was filed in Mississippi. The case joins other cases included in previously established multidistrict litigation (MDL No. 2428, In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation), created to expedite trials for related lawsuits.

*The New York Times* reported in 2012 about questions regarding Fresenius failure to warn non-Fresenius dialysis clinics about possible adverse cardiac events with GranuFlo use. The events might be brought on during dialysis related to a build-up of bicarbonate in patients, the *Times* reported. Clinics began to monitor blood levels for problems, and the product was relabeled.

In June, Fresenius Medical Care Renal Therapies Group began a voluntary recall of Crit-Line blood chambers used in hemodialysis because of product leakage problems. The recall involved 22.6 million



products sold in the United States, Ireland, Spain, Slovenia, Great Britain, the Netherlands, Norway, Mexico, Egypt, and the Czech Republic.

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