

April 14, 2022

Wolfgang Kirsch
Chairman of the Supervisory Board
Fresenius SE & Co. KGaA
Else-Kroener Strasse 1
Bad Homburg, Hessen 61352
Germany

Dear Mr. Kirsch,

We are concerned by allegations of unsafe and discriminatory treatment practices taking place in Fresenius Medical Care (FMC)'s US operations, as described in a complaint to the US Department of Health and Human Services recently filed by SEIU-UHW, the National Health Law Program, and several individuals. With the increasing adoption of mandatory human rights due diligence legislation, including Germany's Supply Chain Due Diligence Act and the EU's proposed directive, the Fresenius SE group bears responsibility and potential risk for the human rights impacts such as these at FMC given the business relationships of the companies. We note indeed that Fresenius SE has taken a group-wide approach to human rights and has identified as particularly important topics to the group access to health care, preventing discrimination, and promoting equal opportunities.¹ We urge Fresenius SE's Supervisory Board to take immediate steps to ensure that the Supervisory Boards of Management AG (FMC's general partner) and FMC are taking appropriate steps to make certain that Fresenius' healthcare services are being provided in a safe and appropriate manner, and to mitigate any potential risk of enforcement actions or private litigation stemming from the practices described in that complaint. At a minimum, these steps should include:

- Commission an independent third-party to review the allegations in the complaint and Fresenius' policies and practices with respect to Ultrafiltration rates ("UFRs"), and to make recommendations to the board to address concerns that the review identifies.
- Commit Fresenius to ensuring that no patient will be subjected to UFRs over 13 ml/h/kg by June 1, 2023, and no UFRs over 10 ml/h/kg by June 1, 2025.
- Immediately address the disparity in the frequency of high UFRs for Latino and Asian American patients compared to White patients.

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High UFRs Pose Risks to US Dialysis Patients, as Fresenius Knows

As the complaint details, hemodialysis serves two primary functions: 1) filtering toxins from the blood, and 2) removing excess fluid from the body. The rate at which this excess fluid is removed is referred to as the Ultrafiltration Rate ("UFR"), and the rate is a function of the amount of fluid to be removed, the patient's body weight, and the length of the hemodialysis session (treatment time).

¹ https://www.fresenius.com/financial_reporting/Fresenius_Annual_Report_2021.pdf, pg. 194.

Medical research has increasingly found that high UFRs are associated with increased mortality and other serious complications, including hospitalization, cardiac events, and loss of consciousness among others. In particular, UFRs above 10 ml/h/kg are associated with higher mortality risk, and this association is even stronger for UFRs above 13 ml/h/kg. Moreover, it appears from medical research that US dialysis patients experience much higher risk of mortality than dialysis patients in other countries: one in four US dialysis patients die within a year of initiating treatment, while six in ten die within five years. These mortality rates exceed the mortality rate for dialysis patients in their first year in Australia, New Zealand, Belgium, Canada, France, Germany, Italy, Sweden, and the UK.

Multiple standard-setting organizations have increasingly focused on limiting UFRs in order to improve patient outcomes. For instance, the Kidney Care Quality Alliance has developed quality measures for dialysis treatment using a UFR of less than 13 ml/h/kg. The National Quality Forum has endorsed this standard, and the Centers for Medicare and Medicaid Services has proposed using UFRs above 13 ml/h/kg as a data collection measure. Finally, the National Kidney Foundation has acknowledged that the 13 ml/h/kg standard “has the most consensus among experts.”

Indeed, the complaint indicates that the risks associated with high UFRs were recognized by Fresenius as far back as 2011, when the company issued a memo to clinicians that acknowledged that UFRs over 10 ml/h/kg increased mortality risk. According to the complaint, this document further stated that “Medical Directors and Attendings are strongly encouraged to implement this clinical practice recommendation to initiate . . . with a minimum dialysis treatment time of 4 hours, while aiming for UFR at ≤ 10 ml/kg/hr.”² Given Fresenius’ formal recognition that high UFRs are risky for patients and should be avoided, the evidence presented in the complaint is particularly concerning.

High UFRs in California Contribute to Patient Risk

The complaint documents that 60% of dialysis facilities with the highest proportion of treatments with UFRs above 13 ml/h/kg had more deaths than expected, compared to only 40% of facilities with the lowest proportion of treatments with UFRs above 13 ml/h/kg. Additionally, the facilities with the most treatments above 13 ml/h/kg had higher rates of hospital readmissions, higher emergency department visits that result in rehospitalization, and more patients with at least one emergency room visit.

The complaint also notes that Fresenius, along with competitors DaVita and Satellite, are responsible for approximately 77% of dialysis facilities in California. As investors, we urge the Fresenius SE Supervisory board to investigate the findings reported in the complaint, assess the company’s internal data, and adopt appropriate policies to ensure that the company is not endangering patients by scheduling sessions of insufficient duration to yield a safe UFR. As the complaint notes, the success that dialysis providers such as Northwest Kidney Centers and Wake Forest University have had in establishing far lower frequencies of high UFRs, around 2% and 7% respectively, makes clear the feasibility of avoiding high UFR sessions.

High UFRs in California Disproportionately Affect Latino and Asian American Patients

The complaint documents the results of an analysis of the incidence of high UFRs across different demographic groups. This analysis finds that Latino and Asian American patients were exposed to high UFRs at a rate 50% higher than White patients. Approximately 20% of dialysis treatments delivered to Asian American patients in California were at a UFR above 13 ml/h/kg, while 14% of treatments

² Document available upon request.

delivered to Latino patients exceeded that level. In comparison, White patients received a high UFR treatment only 11% of the time.

Fresenius Should Proactively Address Patient Care and Disparate Impact Risks

We urge the board to take this complaint seriously and to vigorously investigate its claims. Moreover, given the evidence that high UFRs are associated with increased patient health risks, Fresenius should commit to eliminating such treatments over a feasible time period, such as the three-year period suggested above. Finally, the Fresenius board should take special care to ensure that no demographic minority is disproportionately exposed to high UFRs by identifying facilities that combine high UFRs and a high minority patient population and beginning the process of bringing down UFRs there.

If you and your fellow directors would like to discuss the concerns we raise in this letter, please contact our Research Director Richard Clayton at rclayton@socinvestmentgroup.com.

Sincerely,



Dieter Waizenegger
Executive Director