September 15, 2014

Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Request for expedited review of importation of additional peritoneal dialysis solution

Dear Dr. Hamburg:

The Alliance for Home Dialysis (Alliance) is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote activities and policies to facilitate treatment choice in dialysis care while addressing systemic barriers that limit access for patients and their families, to the many benefits of home dialysis.

We have recently become aware of the ongoing shortage of peritoneal dialysis (PD) solution and want to express our serious concern for how this shortage may impact access to PD for new and current patients with end-stage renal disease (ESRD).

Home dialysis—PD and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. Currently, about 10 percent of U.S. dialysis patients receive treatment at home and approximately 40,000 patients utilize PD.

There has been significant growth in PD since the implementation of the ESRD prospective payment system in 2011, but we fear that this solution shortage could jeopardize the ability of current PD patients to stay on the therapy and the growth of PD in the future. The Alliance is particularly concerned about the ability of new patients to begin PD for the first time.
The Alliance believes strongly in the importance of treatment choice, and has worked to ensure that patients have equal access to all treatment options, including PD. The Alliance also recognizes that for some patients, PD is the only medically-appropriate option given other co-morbidities or conditions. Thus, we urge you to do everything that you can to ensure that all patients have access to this life sustaining treatment modality.

To that end, we ask you to expedite the review of the importation of additional PD solution from well-established manufacturing facilities outside of the United States. We understand that existing foreign plants may have additional capacity but lack the requisite FDA evaluation and licensing. We urge you to work with the owners of those facilities and other key stakeholders to expedite the availability of PD solution from these sites. The Alliance understands that this will not alleviate all of the issues surrounding this shortage, but believes that it would be an important step toward ensuring that new and existing PD patients have better access to this life-saving treatment.

The Federal government has consistently supported the use of home dialysis and thus, the Alliance believes that any efforts you undertake to expedite the availability of additional PD solution would be consistent with the historical intentions of Congress and the Centers for Medicare and Medicaid Services, as well as the needs of the kidney community and public health.

We appreciate your consideration of this request and your attention to this important issue for ESRD patients. If you have any questions, or would like additional information on home dialysis including PD, please contact Lindsay Punzenberger at 202-466-8700.

Sincerely,

Stephanie Silverman
Executive Director

Cc: Doug Throckmorton, MD, Deputy Center Director, Regulatory Programs
    Capt. Valerie Jensen, Associate Director, Drug Shortage Program, Center for Drug Evaluation and Research
Participating Organizations (2014)

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Baxter
Cleveland Clinic
DaVita HealthCare Partners Inc
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care
Greenfield Health Systems
Home Dialysis Plus
Home Dialyzors United
Hortense and Louis Rubin Dialysis Center, Inc.
Medical Education Institute
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare
Southwest Kidney Institute
TNT Moborg International Ltd.