

September 12, 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 to accelerate, to the extent possible, the evaluation and licensure of PD solution manufacturing plants with the capacity to alleviate the current shortage via imports to the United States

Dear Dr. Hamburg:

On behalf of the American Society of Nephrology (ASN), please accept this letter of concern regarding a large and unexpected shortage of peritoneal dialysis (PD) solution. ASN is the world's leading organization of kidney health professionals, representing nearly 15,000 physicians, scientists, nurses, and health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining patient access to optimal quality care, regardless of socioeconomic status, geographic location, or demographic characteristics. The society has recently become aware of the ongoing shortage of PD solution, which raises serious concerns for patient access to the highest quality of care.

ASN urges the FDA to do everything possible to safely expedite the evaluation and licensure of PD solution manufacturing plants located outside of the United States that have the capacity to alleviate the current shortage, and to accelerate the import of PD solution from these plants.

As a result of the current PD shortage, effectively no new dialysis patients may elect to start dialysis on PD. ASN is also concerned that the lack of availability of PD solution jeopardizes current PD patients' access and raises concerns about the kidney community's ability to continue to expand PD use in the future. Most troubling, patients who are starting dialysis for the first time do not currently have access to PD as a modality choice.

PD is an important treatment option from a clinical perspective as well as from patient choice and quality of life perspectives. Many PD patients dialyze at home, which offers more lifestyle flexibility and clinically meaningful improvements in physical and mental health. PD also enables new patients to start dialysis without a hemodialysis catheter. Hemodialysis catheters greatly increase the risk of life-threatening infections and mortality, thus, the implications of preventing new patients from using PD as an alternative are significant in terms of cost and human life.

Both Congress and the Centers for Medicare and Medicaid Services (CMS) have expressed interest in expanding patient access to home dialysis, and their policy indicatives have successfully led to significant increase in PD use in recent years. Use of PD has grown nearly

40 percent since CMS established new incentives in 2008 (26,479 PD patients in 2008 compared to 38,480 in 2012), and all indications were that this positive trend would continue. Disappointingly, the shortage has precluded any growth for the foreseeable several months.

ASN is aware the FDA is working with the United States-based manufacturer that is experiencing the shortfall of this to product attempt to address the situation, but no readily available solution appears feasible in this country at this time. **As such, ASN joins other nephrology health professional organizations in urging the FDA to do everything possible to safely expedite the evaluation and licensure of PD solution manufacturing plants located outside of the United States that have the capacity to alleviate the current shortage, and to accelerate the import of PD solution from these plants.** While these steps will not address the longer-term issues surrounding the PD solution shortage, the society believes it is imperative to begin allowing new dialysis patients to access this modality option as soon as possible.

The society hopes that the concerns articulated and recommendations offered in this letter are helpful as the FDA continues to work to address this shortage, and stands ready to discuss this issue in more detail if it would be helpful.

Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs at rmeyer@asn-online.org or at (202) 640-4659.

Sincerely,



Sharon M. Moe, MD, FASN
President

CC: Capt. Valerie Jensen, R.Ph
Douglas Throckmorton, MD