INTERNATIONAL SOCIETY FOR PERITONEAL DIALYSIS
NORTH AMERICAN CHAPTER

August 29, 2014

To the Federal Drug Administration Agency,

As officers of the North American Chapter of the International Society for Peritoneal Dialysis (ISPD-NAC), we are writing to the FDA to express our *strong concerns* regarding a recent announcement by Baxter Healthcare that there is an unexpected and large shortage in supplies of peritoneal dialysis solution for patients with kidney failure in the US.

Peritoneal dialysis (PD) is the life-sustaining method of dialysis used by nearly 40,000 Americans. Use of PD is increasing rapidly; there was a 14% increase in new PD patients between 2008 and 2011 as compared with a 5% decrease in the preceding 3 years (2005 – 2008). Successful PD growth can be attributed to increasing awareness of the benefits of PD, and is in large part attributable to CMS initiatives that were started in 2008 to encourage greater use of home dialysis.[1] The number of patients choosing PD over in-center hemodialysis (HD) had been expected to rise by as much as 10% in the next 12 months.

To our great dismay, PD growth will effectively stop as a result of the PD solution shortage. As of today, Baxter (who provides dialysis supplies for about 90% of U.S. PD patients) instituted a process to temporarily limit the number of new peritoneal dialysis patient referrals across their entire base of customers, effectively stopping the gains we have made in providing home dialysis to more patients in this country.

The merits of PD are significant: PD provides dialysis *at home*, provides greater patient independence and accommodates working patients better than in-center hemodialysis, and has good medical outcomes. PD is cost effective; according to Medicare, savings of as much as $18,937 per-person/per-year could be obtained with patients opting for peritoneal dialysis instead of in-center hemodialysis. 2 Currently, CMS spends more than $29 billion a year to treat kidney failure. If an additional 5% of new dialysis patients chose PD over in-center HD, a potential cost savings of more than $350 million could be realized.

ISPD-NAC believes that each and every single kidney failure patient in the US deserves the right to have the best dialysis treatment for his individual case, whether it is at home or in-center. That decision must be made based upon patient choice and medical concerns, not upon supply inventories. Patients and doctors must have all dialysis options available; choice is vital in an era of both patient centered care and cost constraints. If manufacturers in the U.S. cannot supply life-sustaining dialysis solution, it is not an option to deny PD to patients. The repercussions of making patients start in-center hemodialysis (instead of PD) with a

hemodialysis catheter are significant and include an increased risk for life-threatening infections. Your colleagues at CMS, who are well aware of the dangers of HD catheters, could elaborate further on why we must avoid HD catheters in patients who were otherwise planning to start PD.

The best option for maintaining adequate supplies of PD solutions is unclear. Unfortunately, the only other major U.S. based manufacturer, Fresenius Medical Care, has stated that it does not have capacity to make up the shortfall. The leading option ISPD-NAC would suggest is for the FDA to consider the importation of PD fluid, specifically via an accelerated process for evaluating and licensing well-established PD solution manufacturing plants that have capacity, but are outside the United States. We understand there may be plants in Western Europe capable of assisting in this challenging situation.

Finally, we would like to emphasize that ISPD-NAC is an independent society of medical professionals committed to improving the quality and availability of PD worldwide through advocacy, education and research. We do not represent any manufacturer or provider in the dialysis industry. Our sole interest in this matter is in maintaining and increasing access to high quality PD for all kidney failure patients who wish to have it as their dialysis modality.

Respectfully,

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on behalf of the North American Chapter of the International Society for Peritoneal Dialysis

[1] p.20396 Federal Register / Vol. 73, No. 73 / Tuesday, April 15, 2008 / Rules and Regulations

[2] Federal Register / Vol. 73, No. 73 / Tuesday, April 15, 2008 / Rules and Regulations