April 23, 2013

Jeffrey Shuren, M.D., J.D.
Director
CDRH - Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-5429
Silver Spring, MD 20993

Dear Dr. Shuren:

The Alliance for Home Dialysis appreciates the Food and Drug Administration's (FDA) work to ensure the safety and effectiveness of critical drugs and devices that support home dialysis patients. In order to drive innovation in any sector, it is important that the FDA works with stakeholders, including patients, manufacturers, and providers, to provide clear guidance on the requirements necessary to bring products to market that will lead to improvements in health.

The Alliance for Home Dialysis is a coalition of kidney dialysis stakeholders, representing patients, clinicians, providers and industry, that 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. Congress has long recognized the importance of ensuring that beneficiaries have access to a range of safe and effective modalities, and the Alliance believes this should include nocturnal home hemodialysis (NHHD).

To that end, the Alliance for Home Dialysis urges the FDA to create a clear pathway for clearance of NHHD systems via the 510(k) process. Specifically, the Alliance encourages the FDA to expand on its 2008 guidance to provide manufacturers with specific data expectations to determine not only the efficacy but also the safety of new NHHD systems. Additional clarity would assist with study plans and submissions, as well as possibly improve the likelihood of future development in NHHD. This request for additional clarity is not meant to suggest that pre-Investigational Device Exemption (IDE) meetings will no longer be desired or necessary as manufactures greatly value the exchange of information that occurs in those meetings with the FDA. The Alliance is simply seeking additional guidance to help innovators of new NHHD devices to prepare for pre-IDE meetings in a manner that is responsive to the expectations of the FDA.

A treatment option that has been utilized by physicians and patients since the mid-1960's, NHHD uses longer and more frequent dialysis sessions than conventional dialysis and is associated with positive clinical outcomes such as improved blood pressure, increased survival, and an enhanced quality of life.[1,2]

[1] Tennankore, K. K. *et al. Nat. Rev. Nephrol.* 8, 515–522 (2012)
[2] Young BA et. *Clin J Am Soc Nephrol* 7: 2023–2032, 2012.

Additionally, because patients can undergo dialysis while sleeping, NHHD provides patients with more time for daily life activities, potentially leading to societal and employment benefits.

Despite an Advisory Panel meeting in 2005 and a guidance document issued in 2008, the FDA has not yet cleared any device that would facilitate NHHD. At the 2005 Advisory Panel meeting to discuss NHHD, the FDA outlined the medical literature available on the subject of nocturnal dialysis, as well as the issues to be considered in developing clinical trials. There, Advisory Panel members commented on the safety features that systems should include in order to make the practice of nocturnal hemodialysis as safe as possible.

Following the Advisory Panel meeting, in 2008 FDA issued a guidance document, entitled *Guidance for Industry and FDA Staff: Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis* ("Guidance Document"). The Guidance Document indicates that sponsoring companies should plan to conduct prospective studies examining use of nocturnal home hemodialysis compared to in-clinic use of the system. Suggested endpoints include adverse event tracking, measures of ability to successfully perform treatment (e.g., achieving desired kt/V in prescribed treatment time), and reliability of the device. No other specifications for trial endpoints were provided. The Guidance Document clarifies that the purpose of any study would be to demonstrate the safety and effectiveness of nocturnal hemodialysis systems.

The Alliance considers the 2008 guidance a strong starting point in providing a clear route to clearance for the NHHD indication in the 510(k) pathway, but we believe substantial benefit could be derived from providing manufacturers with specific data expectations to determine not only the efficacy but also the safety of new NHHD systems. The Alliance maintains that the intended use of NHHD is appropriate for clearance via the 510(k) pathway, given that a product intended for NHHD has the same general intended use as a product intended for home dialysis, namely dialysis in the home environment. However, the Alliance understands that there are different safety considerations for a device that is used during sleep compared to one that is used during waking hours.

Thus, we request that the FDA formally clarify the categories and endpoints required to demonstrate a safety profile, many of which were discussed on an October 25, 2012 call with the Alliance, which would be an important step in providing more certainty to manufacturers looking to develop innovative solutions for dialysis patients. Additionally, we request that the FDA clarifies the requirements to demonstrate an acceptable level of risk so that manufactures can work to incorporate mitigation strategies that would keep products intended for nocturnal home hemodialysis within the same class II categorization as existing home dialysis products.

If you have any questions or need additional information, please contact Amy Redl at amy@homedialysisalliance.org or 202-280-1963. For a list of organizations participating in the Alliance's working groups, please visit our website at www.homedialysisalliance.org.

Sincerely,

Amy Redl, Director of Federal Affairs
Alliance for Home Dialysis

cc: Christy Foreman, Director, Office of Device Evaluation

Signing Alliance Members

American Association of Kidney Patients

American Kidney Fund

American Nephrology Nurses Association

American Society of Nephrology

American Society of Pediatric Nephrology

Baxter

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Washington University School of Medicine, Renal Division