National Home Infusion Association
Providing solutions for the infusion therapy community

February 19, 2014

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

Dear Commissioner Hamburg:

I am writing with respect to the National Home Infusion Association's (NHIA's) concerns about the wide-spread promotion of Section 503B facilities, otherwise known as outsourcing facilities. Since the enactment of the Drug Quality and Security Act last year, the Food and Drug Administration (FDA) and Patient Safety Organizations (PSO) have been urging healthcare providers and regulating bodies to demand that all compounded drugs must come from Section 503B facilities. In effect, the FDA has been informing providers that 503B facilities are appropriate for all compounding needs. We strongly believe that is not accurate and that there is a continuing need for certain pharmacies to operate as 503A facilities. As the FDA and PSOs work to ensure compounded drug safety, NHIA believes it is important that the FDA fully understand and value the role 503A traditional compounding pharmacies play in the provision of infusion drug therapies.

Infusion therapy (the administration of medications into the bloodstream via needle or catheter) is the medically necessary treatment for many patients with cancer, serious infections and other conditions. Providing infusion therapy in a patient's home involves not only the delivery of medication, but also the specialized equipment, supplies, and professional services, including pharmacy compounding, necessary to ensure safe and effective administration of the therapy. Home infusion drugs are compounded patient specific pursuant to a prescription often with the need to start administration of the drug the same day.

The FDA's recent efforts to publicize its new regulatory authority over outsourcing facilities have emphasized that the FDA will apply the current Good Manufacturing Practice (cGMP) standards to these facilities. The FDA also has indicated that it may consider new cGMP standards for outsourcing facilities. As the FDA investigates new cGMP standards, it will be important that the FDA re-assess the sterility testing requirements included in the cGMP standards that were developed to regulate drug manufacturing practices. The FDA set out the sterility testing foundation of cGMP standards in regulations (21 CFR 211.§165) by instituting batch sampling sterility testing requirements. Under this requirement, sterility testing must be performed on a sample of

each batch of product that is shipped from the facility. Sterility testing can take several days to show whether the product is tainted.

This requirement does not translate to home infusion pharmacies and could cause considerable harm to their patients. When an infusion pharmacy compounds a drug that is specific for a patient, there is no batch of drugs from which to derive a sample. In many cases, the drug must be administered within hours of compounding due to patient need and drug efficacy. Thus, the cGMP and specifically the sterility testing procedures within the cGMP cannot be applied as currently written to patient-specific compounded products. It is for these reasons that the United States Pharmacopeia (USP) developed standards for compounding these drugs to ensure sterility of the product, rather than for post-product testing.

There are hundreds of medications that are used in home infusion and by health care providers that are compounded specifically for the patient. Examples of these drugs include:

- Parenteral nutrition;
- Pain management;
- Antibiotic treatments; and
- Oncology treatments.

As indicated above, unless the FDA makes significant changes to cGMP sterility testing standards, these drugs will only be available from Section 503A regulated facilities, i.e., traditional compounding pharmacies.

The FDA, the Centers for Medicare and Medicaid Services (CMS) and other organizations that are reviewing their policies regarding compounded drug products should recognize that currently some drugs simply cannot be prepared by a section 503B facility if the manufacturing cGMP sterility testing requirement is applied to such facilities. In exploring changes to the cGMP standards for outsourcing facilities, the FDA should consider mirroring USP standards to ensure the sterility of the compounded products. If the FDA does not change the sterility testing procedures in cGMP, CMS and other drug purchasers should recognize that patient-specific compounded products simply will not be able to be purchased from outsourcing facilities. NHIA warns that a blanket "outsourcing facility only" policy for compounded drug products will result in certain drugs being unavailable, thus potentially harming patients.

NHIA urges the FDA to be mindful of this issue when updating cGMP standards, regulating 503A facilities, and how the FDA promotes outsourcing facility purchasing. As the FDA carries out the implementation of the Drug Quality and Security Act NHIA stands ready to work with the Agency to ensure lifesaving drugs can be compounded and administered safely.

Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Legislative Affairs, at (703) 838-2664 or kendallvanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.

Sincerely,

Russell Bodoff
President & CEO
National Home Infusion Association