January 20, 2021

Maria Serpa, PharmD
Chair, Enforcement and Compounding Committee
California Board of Pharmacy
2720 Gateway Oaks Blvd., Ste. 100
Sacramento, CA, 95833

Re: Compounding of Methylcobalamin

Dear Ms. Serpa:

The National Community Pharmacists Association (NCPA) writes today to oppose the proposed changes by the California Board of Pharmacy on compounding of methylcobalamin (MeCbl), emphasizing the need to maintain appropriate patient specific compounded MeCbl through 503A pharmacies licensed in the state of California. NCPA applauds the Board's vigilance in pursuit of patient safety yet we urge the Board to be judicious in its forthcoming decision as not to make an error in judgement, establishing an unsettling precedent for the rest of the country to follow, increasing costs for and limiting patient access, and ultimately disrupting patient care. Considerations such as these that will create burdens for patients yet yielding no significant differences in perceived safety or efficacy is unreasonable. **NCPA urges the Board to cease this pursuit at the hearing on Wednesday, January 20th, 2021.**

NCPA represents America's community pharmacists, including more than 21,000 independent community pharmacies across the United States and 2,022 independent community pharmacies in California that employ over 22,000 employees who filled over 116 million prescriptions last year. Our members are small business owners who are among America's most accessible healthcare providers, they play a critical role in ensuring patients immediate access to patient specific compounded medications and provide an expanding set of healthcare services to millions of patients every day.

MeCbl, the active form of cyanocobalamin (vitamin B12), is an injectable drug not commercially available and is listed on the FDA category list 1 for drug bulk substances, which permits the compounding of it by 503A pharmacies for safe use by patients under the direct supervision of a licensed practitioner. Useful for patients who lack intrinsic factor and thereby are unable to absorb the drug from the GI tract, MeCbl IM or IV injections bypass the need for the intrinsic factor and provide the patient with an appropriate physician directed dose. Additionally, MeCbl is used to treat nutritional diseases, autism, Alzheimer's diseases, neuropathic pain, and rheumatoid arthritis.

The spectrum of patients that will be affected should the Board decide to shift compounding of MeCbl to 503B pharmacies can be gleaned from its many uses. Patients who have relied on access to MeCbl from their local community pharmacies now have to consider other pathways to access this medication. Since 503B pharmacies may only compound MeCbl for office use, unless licensed as a pharmacy in CA, a trip to the doctor's office is warranted every time a patient's dose is due (consider patients who require multiple injections on a weekly basis),

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increasing the total cost (i.e. lost work time, transportation fees) for accessing the drug. Patients located in underserved rural areas will especially be affected. With these additional burdens and no tangible or significant benefit to the patient, office visits can be missed, adherence plummets, and conditions worsen. In addition, of the 901 active sterile compounding licenses that have been issued in CA, 29 are active 503B licenses, 4 of which are physically located in CA; only one of these 503B pharmacies currently compound MeCbl compared to the hundreds of 503A pharmacies with a proven track record of compounding patient specific MeCbl safely.

As the Board rightfully is concerned with end product testing of batches prior to patient use, NCPA highlights that such testing is not proof of sterility, therefore, the Board should focus on ensuring good practices throughout the overall compounding process. Furthermore, during the Center for Drug Evaluation and Research (CDER) Compliance Conference last week, the Food and Drug Administration (FDA) emphasized that sterility assurance involved a wholesome approach throughout the compounding process to ensure product quality; independently, sterility testing, finished product testing, media fills, and environmental monitoring fail to establish or ensure the latter.[1] The FDA has shut down 503B pharmacies that only use sterile FDA-approved products as their starting material, showing that product safety goes beyond the starting material, cGMP, or end product testing. Rather it is the operations performed routinely to ensure good practices that is of importance. If the Boards wants 503A pharmacies to perform end product testing prior to medication release to the patient, then further considerations should be focused on this point.

Decisions as wide reaching as what the Board is considering must not be based on perceived safety, rather efforts ought be focused on how the Board may optimize safety by adopting measures under legal authority which do not unnecessarily burden the compounding pharmacies and more importantly, the patients. NCPA asks that the Board strongly consider the following:

- *Is the Board's concern based on credible evidence, rare bad actors, or markers of speculation?*
- *Is the Board's concern significant? Can it be alleviated with informed choice or voluntary patient confirmation?*
- *Does addressing this concern require a new law or do existing laws or regulations already address it? Will additional narrowly tailored sterility testing requirements alleviate this concern?*

NCPA appreciates the opportunity to provide comments and remains hopeful in the Board's capabilities to ensure patient safety of compounded MeCbl products while maintaining a much needed access - banning compounding of MeCbl by 503A compounding pharmacies is not a sound decision. **Such a ban is not rational as it will disrupt the ease of access to an essential medication for many California residents without providing significant benefits in safety or efficacy, and it creates a precedent in which other states may follow**. **NCPA emphasizes that the Board should work with its many licensed 503A pharmacies to ensure a safe product for Californians and not limit supply to outsourcing facilities**. Thank you for your time and consideration. If you have any questions, or if we can be of any assistance please do not hesitate to contact Ademola Are at ademola.are@ncpa.org.

Sincerely,

[1] U.S. Food & Drug Administration: Cleanrooms & Cleanroom Behaviors: Why they Matter

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VP, Policy & Government Affairs Operations