

Damoth, Debbie@DCA

From: Skye Morland <skymorland@gmail.com>
Sent: Wednesday, July 31, 2024 10:14 AM
To: Damoth, Debbie@DCA
Subject: Comment: 1736.9 e

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Proposed Language: (e) When a bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, **be a USP Chapter 797 Category 1 substance**, or be listed 21 CFR 216, unless authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.

Comment:

The proposed language in 1736.9 e excludes category 1 substances. I would like share with you why it is critically important that these category 1 substances be protected and expressly included as approved substances for compounding pharmacies. Compounding pharmacies are the only way to provide controlled and correct dosing of these substances which is critical for people with absorption issues and metabolic disorders. I will focus on methylcobalamin because this impacts me personally, but similar situations arise for many of these substances.

A rare genetic disorder that impacts the ability to process B12 into its active forms including methylcobalamin runs in my family. Vitamin B12 methylcobalamin deficiency, can lead to severe and irreversible health consequences if not properly addressed. After a certain stage, the impacts of B12 deficiency become non-reversible, potentially resulting in permanent neurological damage. This can manifest as:

1. Permanent loss of sensation in limbs
2. Severe motor impairment, including the inability to walk
3. Cognitive decline that can range from mild impairment to severe cases resembling dementia or even mental retardation

Compounding pharmacies are uniquely positioned to address this critical health issue. They are the only ones who can create these B12 shots that provide precision required to ensure that the correct dosage is provided, the correct absorption happens, so the required B12 blood levels are reached. This is especially important for people with absorption issues, as it is impossible to know how much oral B12 will enter their system. It is also important to note that the vitamin industry is largely unregulated. There is no guarantee that the dosage in over-the-counter supplements is even correct. As such, relying solely on oral over-the-counter supplements can result in over or significantly under amounts in the bloodstream, causing further damage to a person's health.

In conclusion, the availability of compounded B12 methyl through pharmacies is essential for ensuring that patients with genetic, metabolic, and/or absorption issues receive the precise treatment they need to prevent irreversible neurological damage and maintain their overall health.

The issue is that many of the genetic and metabolic issues that are treated with Category 1 substances are rare conditions that do have a voice because of their small numbers. Taking away access to these Category 1 substances damages health and right to safely compounded and sometimes lifesaving substances for vulnerable and often overlooked populations.

The California State Board of Pharmacy's mission statement is to protect the health and safety of the people of California. As such, I request that you stand up for the HEALTH and SAFETY of my family members and people like them who rely on Category 1 substances and revise 1736.9 e to expressly include these Category 1 to ensure the health of all California citizen.

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