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#STOPTHEBOP
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Public Comment on Proposed Amendments to Title 16 CCR Sections 1735-1738

Dear Members of the California State Board of Pharmacy,

I am writing this public comment on behalf of Stop the BOP, a nonpartisan patient-led movement advocating for the protection of access to sterile compounded medications that are essential to the lives of hundreds of thousands of Californians and utilized in countless medical communities across the nation and around the world.

The proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738, impose unnecessary restrictions on access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+. These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures.

In the wake of the Palisades and Eaton fires, Californians are grappling with the health consequences of prolonged toxic smoke inhalation, including toxin buildup in lung tissue. For many, the only effective treatment to address these toxins is nebulized and intravenous glutathione. These therapies are utilized by firefighters, Lyme Disease and Long COVID patients, and individuals with conditions like ME/CFS and methylation impairment. Denying access to these critical treatments endangers vulnerable populations and ignores the unique health challenges faced by our state.

At the January 8 Board Meeting, Board Member Maria Serpa claimed these regulations do not exceed USP and FDA requirements, but *this is patently false*.

- **USP does not require full stability studies for Category 1 or 2 sterile compounding.** These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to $30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders.
- The **additional documentation of clinical circumstances** for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are

already treated like any other active ingredient under FDA guidelines, with no such documentation mandate.

- The requirement to perform multiple tests on APIs, including **tests listed in USP Chapters above 1000** (informational-only chapters), is both excessive and unprecedented. California would be the only state enforcing such standards on 503As, further restricting access without improving safety.

These burdensome regulations will have devastating consequences, especially for patients needing compounded treatments tailored to their specific health needs which is the entire purpose of 503A compounding pharmacies. For example, while pharmacies may justify the cost of stability studies for a generic glutathione multiple-dose vial, they will not be able to produce more individualized options such as essential preservative-free formulations or combinations. In essence, these regulations force 503A pharmacies to function as 503Bs which is, in a word, absurd.

Relevant Example and Public Process

What is most disturbing is the Board's persistence in moving forward with these harmful regulations despite overwhelming public opposition. This is not how a government body is supposed to operate.

USCIS Example

Recently, USCIS proposed changes to the naturalization process, including a multiple-choice civics test to replace the current oral exam. The same way the Board of Pharmacy has worked very hard on these widely opposed updates to Title 16, USCIS worked tirelessly on these naturalization updates which they believed would improve fairness. However, after USCIS received 1,300 public comments—fewer than the Board of Pharmacy has received in total—they chose NOT to proceed because the vast majority of comments opposed the changes. (Public commenters explained how, in fact, these updates would hold immigrants to a higher standard and presumes they have advanced westernized test-taking abilities.)

This is how the public process works: as a regulatory body, **your job is to listen to public comments and adjust your actions accordingly**. Under no circumstances is it appropriate to hold it against the public that the Board's hard work went into a proposal when said proposal ultimately harms the public interest. To force it on them anyway is petty and tyrannical.

Doctors, organizations, patients, and firefighters have repeatedly told you that they do not want these regulations. The Alliance for Pharmacy Compounding and numerous individual pharmacists have also voiced strong opposition. And yet, you continue to move forward, closing your ears to the outcry from those directly affected by your decisions. Ignoring public input and prioritizing the voices of a few individuals at the top—particularly taxpayer-funded lawyers at the Department of Consumer Affairs and an Executive Officer who clearly does not have the public's best interest in mind—suggests ulterior motives.

As California faces an unprecedented public health crisis due to widespread toxic smoke exposure, including asbestos, lead, microplastics, and potentially thallium, this Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to access critical treatments, preserve access by fixing this proposal.

Our asks are simple:

1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications.
2. Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied.
3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only.
4. Amend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors.

The Board's mission should be to protect public health—not restrict access to therapies that enhance patient outcomes. I urge you to reconsider these proposed regulations and prioritize the well-being of Californians who depend on compounded medications for survival and quality of life.

Thank you for your attention to this critical matter.

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