PROMPTS FOR PUBLIC COMMENTERS Board of Pharmacy Public Meeting, July 31, 2024

- Personal Impact: Describe how the proposed regulations would affect your personal health or the health of someone you care about. For example, explain how losing access to a specific compounded medication would impact your daily life, ability to work, or overall well-being.
- Chronic Illness: Explain the importance of compounded medications like Glutathione and Methylcobalamin for managing chronic illnesses such as long COVID, Lyme Disease, and ME/CFS. Discuss how these treatments are often the only effective option for managing symptoms and maintaining quality of life.
- 3. **Firefighters:** Discuss the crucial role these compounds play in detoxifying firefighters from hazardous exposures. Share stories or statistics about how these treatments help firefighters recover from exposure to toxins and chemicals encountered in the line of duty.
- 4. **Lack of Alternatives**: Highlight the lack of effective alternatives to compounded medications and the potential health crises that could result. For example, explain how over-the-counter supplements are often ineffective compared to compounded IV infusions or subcutaneous injections and how this would leave many without viable options.
- 5. **Scientific Evidence**: Present scientific studies or evidence supporting the efficacy and safety of these compounded medications. Cite specific research findings or expert opinions that demonstrate the benefits and necessity of these treatments.
- 6. **Comparison to Other States**: Point out that these treatments are easily accessible in other states and question why California should be different. Discuss how this inconsistency could force you or members of your community to move away from California and the injustice of this.
- 7. **Transparency Issues**: Talk about the lack of transparency and clarity in the proposed regulations and the public comment process. If you were at the June 18 hearing, highlight specific instances where the Board's responses were generic and undermining genuine public participation.
- 8. **Legal Overreach and Starting Over**: Discuss how the Alliance for Pharmacy Compounding found 57 specific instances where the regulations exceeded federal and Pharmacopeia standards without justification. Explain how the slight softening in language in the latest version does not do enough, and how the regulations should be sent back to committee due to broad public disapproval.
- 9. Enforcing regulations before they exist: You can call out the Board of Pharmacy (particularly Executive Officer Anne Sodergren and Compounding and Enforcement Committee chair, Maria Serpa) for enforcing regulations that do not exist over the past 4 years, for penalizing pharmacies for producing glutathione and methylcobalamin despite the fact that they're legal. Softening the regulatory text in this latest version does not undo the damage done the past 4 years to scare pharmacies out of producing and selling these medicines in California.
- 10. **Assembly Bill 973**: Describe how the Board is exploiting Assembly Bill 973 to impose overly stringent regulations. Explain that while AB 973 was intended to ensure alignment with Pharmacopeia standards, it is being misused to justify excessive deviations from federal norms.
- 11. **Economic Impact**: Discuss the potential economic impact on compounding pharmacies and the broader healthcare industry in California. For example, talk about how these regulations could lead to the closure of small pharmacies, job losses, and reduced access to healthcare services.

- 12. **Public Health**: Argue how these regulations could negatively impact public health by restricting access and raising prices on essential compounded medications. Explain how reduced access could lead to worsening health outcomes for many individuals who rely on these treatments.
- 13. **Patient Stories:** Share specific stories of patients who have benefited from these compounded medications. For example, describe a patient's journey and how a particular compounded treatment has been life-changing or life-saving.
- 14. **Medical Professional Opinion**: If you are a doctor or pharmacist, provide your professional opinion on why these regulations are harmful. Discuss your experience with compounded medications and how they have positively impacted your patients' health.
- 15. **Opposition from Medical Organizations:** Mention the opposition from respected organizations like Kaiser Permanente, Cedars-Sinai, the California Hospital Association, and others. Explain how it concerns you that the Board of Pharmacy is still moving forward despite this broad opposition.
- 16. **Personal Testimony**: Provide a personal testimony about how these treatments have improved your quality of life. For example, describe how a specific compounded medication has allowed you to manage your illness and maintain your independence.
- 17. **Call for Reconsideration**: Urge the Board to reconsider the regulations, citing the lack of public support and lack of scientific evidence. You may mention that the Board's motivation does not seem in the best interest of the public. Encourage the board to send the regulations back to committee (*This means the regulations will have to be scrapped.*)
- 18. **Potential Harm**: Discuss the potential harm that could come from restricting access to these medications. For example, explain how the loss of access could lead to increased hospitalizations, worsening health conditions, and higher healthcare costs.
- 19. **Community Impact**: Talk about how these regulations could affect your community and its members. For example, describe the ripple effects on local healthcare providers, patients, and overall community health and well-being.
- 20. **Call to Action**: End with a call to action, urging the Board to listen to the voices of the people and protect access to essential treatments. Encourage others to speak up, get involved, and join the fight against these harmful regulations.
- 21. **Pernicious Anemia**: Explain how the Pernicious Anemia community depends on B12 shots and how many can only tolerate methylcobalamin, the most bioavailable form. If the board insists on restricting this compound, the pernicious anemia community will be directly affected. (The synthetic form, cyanocobalamin, contains cyanide which is toxic to many. This form also requires methylation which is impossible for patients with certain health conditions like the MTHFR gene mutation.)
- 22. **Lyme Disease, Long COVID, ME/CFS**: Explain how chronic illnesses such as these have very few treatment options after standard therapies fail. These are patients who have found relief from glutathione, NAD+ and methylcobalamin. These are treatments needed for maintenance, and many patients could relapse if they are taken away.
- 23. **Ask about the BOP's Motivation**: Call out Chairwoman Maria Serpa (the architect of these regulations) and raise the fact that the board has not offered scientific or safety-based reasoning for the regulations. Call out Executive Officer Anne Sodergren for targeting compounding pharmacies. You can rhetorically ask the board to question Maria Serpa, who clearly does not have patients' interest in mind.