April 19, 2021

California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Consideration for Signing FDA's Memorandum of Understanding

McGUFF COMPOUNDING PHARMACY SERVICES, INC.

Dear California Board of Pharmacy Enforcement Committee,

McGuff Compounding Pharmacy Services, Inc. (CPS), serving thousands of patients across 48 states, is concerned about the Memorandum of Understanding (MOU) that the Food and Drug Administration (FDA) finalized in October of 2020.[1] CPS understands the document is inherently flawed in that it leaves individual states to investigate and respond to complaints related to compounded human drug products and to monitor interstate distribution of inordinate amounts of compounded human drug products. There are also administrative burdens placed squarely on the California State Board of Pharmacy (the Board) with related costs incurred to the state to carry out the various reporting tasks required by the MOU. However, we strongly believe that for the following reasons, by not signing the MOU, the health and safety of Californians will be jeopardized and in-state California pharmacies harmed.

1. ***California Compound Quality Standards Exceed Other States:***
   Thanks to the Board's strong efforts in advocating for patient safety concerning pharmaceutical compounds, California has some of the highest quality expectations for compounded drugs in the country. This is reflected in the state's compounding regulations, which meet and often exceed the minimum standards required by the United States Pharmacopoeia (USP) chapters <795> and <797>.[2, 3, 4] For perspective, in 2018, Pew Charitable Trusts reported that California was one of only ten states having strong standards for sterile compounding practices that are equivalent or stricter than USP <797>.[5] Therefore, it can be argued that preparations compounded by pharmacies in California achieve a higher level of quality over compounds prepared in most other states.

2. ***503B Outsourcing Facilities are Not the Complete Answer to Interstate Commerce of Compounded Drugs:***
   The Board and the FDA may prefer patients obtain sterile compounds from FDA registered 503B facilities, however there are currently only 29 outsourcing facilities actively licensed by the California Board of Pharmacy out of the 69 503B outsourcing facilities currently registered with the FDA.[6, 7, 8] As per an outsourcing facility product report search, each of the facilities licensed in California focusses on manufacturing select therapeutic specialty compounds and do not offer wide-ranging product lines to meet the needs of every unique patient.[9, 13]

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Section 503B(d)(4) of the FD&C Act defines an outsourcing facility as a facility at one geographic location that is engaged in compounding sterile drugs.[10] As such, access to non-sterile compounds are often limited to coming from 503A pharmacies.

While 503B outsourcing facilities are key to mass-producing quality compounds, they are limited to the Category 1 list for the bulk drug substances they can use to prepare finished compounds or face mass-production challenges and limitations in compounding with FDA approved drugs as starting materials.[11] Whereas 503A pharmacies can prepare compounds with bulk active ingredients having a USP-NF monograph, those that are found in FDA approved drugs, and those on the Category 1 bulks list.[12] Therefore, signing the MOU is critical to maintaining patient access to compounded medications that can only come from 503A pharmacies.

In 2019, the Office of Inspector General reported that 44.8% of hospitals surveyed faced challenges in obtaining all the non-patient-specific drugs they sought from 503B outsourcing facilities. It was also found that 55.8% of hospitals that obtained non-patient-specific drugs from outside compounders relied on more than one facility for locating compounded medications. The report additionally revealed that hospital's needs are not being met by outsourcing facilities to effectively serve drug shortages.[13]

These findings collectively reiterate the importance of maintaining access to various compounds across numerous specialties with the help of 503A compounding pharmacies. Therefore, to maintain national patient access to various medications from 503B outsourcing facilities as well as from 503A pharmacies, CPS encourages all states, and particularly California, to sign the MOU. As of March 18, 2021, the NABP reports that 42% of the country is considering signing the MOU.[14] Given the propensity for California to be a leading force in shaping national public policies, if California signs the MOU, it's possible the nation will follow. Conversely, if California does not sign, it's also possible the nation will follow.

3. A Centralized System for Tracking Complaints and Interstate Commerce of Compounds will Enhance Patient Safety:

It is the FDA's intention that a MOU be signed by all states so that entities that ship compounds across state lines can be regulated appropriately.[1] The MOU also requires the states to track and respond to complaints related to compounded human drug products. If California does not sign the MOU, then pharmacies will be allowed to ship 5% of compounds across state lines. Additionally, a pharmacy complaint tracking system will likely continue to be lacking. If 503A entities are not appropriately regulated and tracked for compliance and quality, patient safety could be compromised in pharmacies that fall under the 5% threshold. Given the New England Compounding Center's and other past compounding-related

tragedies as well as the Board's evident intent to maintain patient safety, it makes sense that the Board would want to sign the MOU since these ideologies align.[15]

4. ***Maintain 503A Pharmacies as a Part of the National Emergency Solution:***
   Since the COVID-19 pandemic began in 2020, the nation witnessed a disruption in a drug supply chain that is already constantly taxed with numerous drug shortages.[16, 17] In response, the FDA granted temporary guidance documents allowing 503A pharmacies flexibility for assisting pharmaceutical manufacturers and 503Bs in maintaining the drug supply chain.[18, 19] If California (and other states) do not sign the MOU, pharmacies will not obtain out-of-state licenses in the first place and will not be ready for aiding the next widespread national crisis.

5. ***Maintain a Safe and Fair Marketplace in California:***
   The California Department of Consumer Affairs mission is as follows,

> ***"We protect California consumers by providing a safe and fair marketplace through oversight, enforcement, and licensure of professions."***
>
> -California Department of Consumer Affairs

The California Board of Pharmacy mission is as follows,

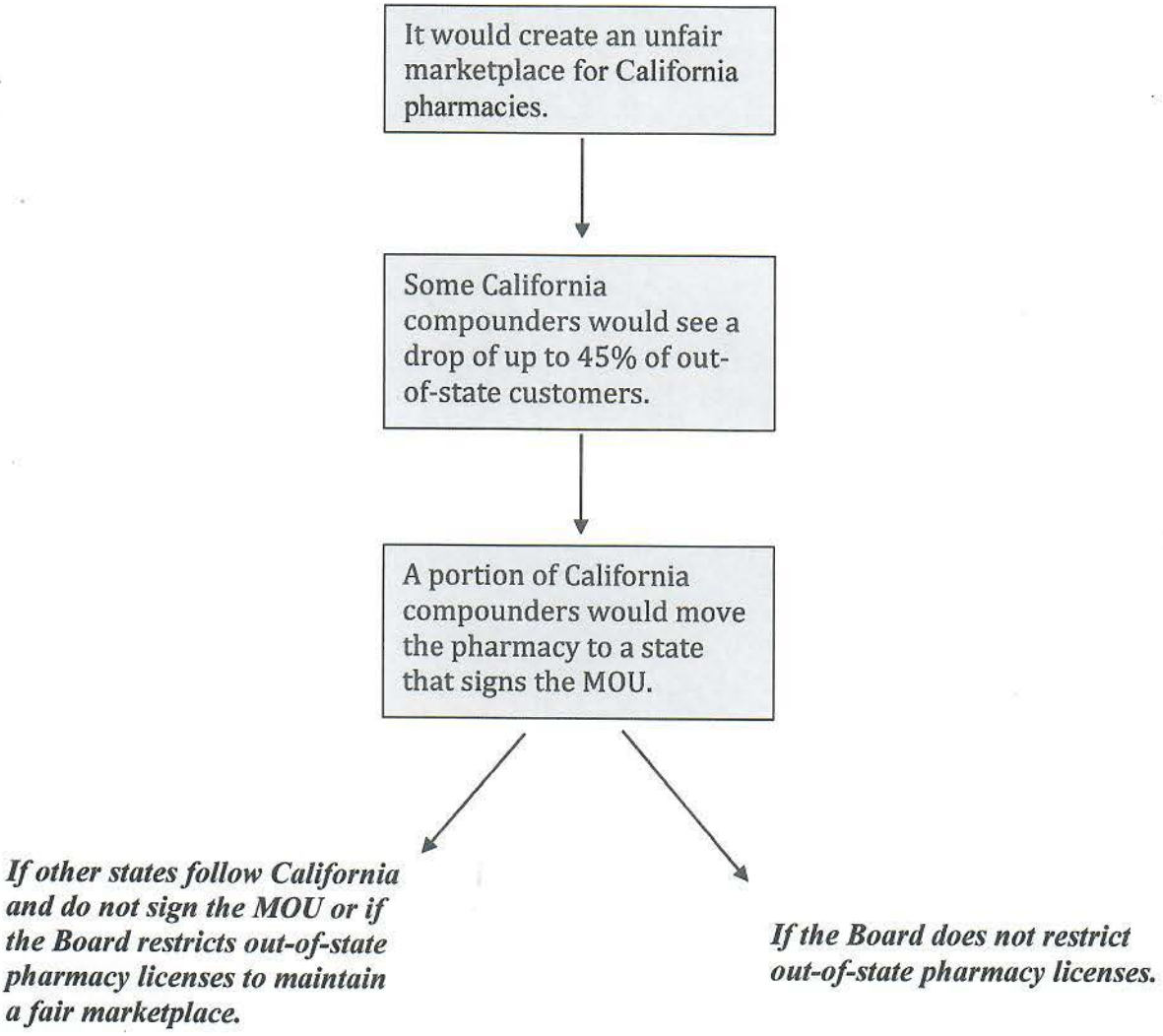
> ***"The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement."***
>
> -California Board of Pharmacy

The MOU as written does not restrict reciprocity of the 5% rule, meaning if California chooses not to sign the MOU, the same 5% restriction into California does not apply for other states that do sign it.[1] This means if California does not sign the MOU and for example Texas does, California would likely see a drop in in-state-compounded preparations with an increase in compounds being shipped into California from Texas (see Figure).

This is because a portion of resident compounders would likely be lost to other states that sign the MOU to prevent losing up to 45% of their patients by staying in California.[1] This is also because some California pharmacies would likely close down altogether due to an unfair marketplace practice not imposed by other states that sign the MOU. As a result, a fiscal impact analysis would likely see a decrease in resident pharmacy and sterile compounding license fee revenues as well as a decrease in the California state tax base. Non-resident license fee

revenues may decrease from other states if those locations follow California's lead in not signing the MOU or if the Board restricts out-of-state pharmacy licenses to maintain a fair marketplace in California. In this scenario, California would also lose access to unique compounds prepared in non-resident pharmacies which are not made by resident pharmacies. Conversely, non-resident license fee revenues may increase in those states that do decide to sign the MOU and if the Board does not restrict out-of-state licensees. In that scenario, there would be fewer quality compounders residing in California and additional non-resident compounders, putting the burden on Board inspectors to perform many more out-of-state sterile compounding license inspections over in-state inspections.

Figure 1: What Happens if the Board Does NOT Sign the MOU?



Fiscal Outcome	Health Outcome
A decrease in resident pharmacy & sterile compounding license fee revenues, a decrease in the California state tax base, and a decrease in non-resident license fee revenues.	A decrease in patient access to compounds prepared in resident and non-resident pharmacies.

Fiscal Outcome	Health Outcome	New Burden
A decrease in resident pharmacy & sterile compounding license fee revenues, a decrease in the California state tax base, and an increase in non-resident license fee revenues.	A decrease in patient access to compounds prepared in [quality] resident pharmacies and an increase from non-resident pharmacies.	An increase in out-of-state sterile compounding license inspections.

Since California is among the minority of states having strong standards for sterile compounding practices that are equivalent or stricter than USP <797>,[5] preparations compounded by pharmacies in California may achieve a higher level of quality over those prepared in other states. Therefore, in order to protect and promote the health and safety of Californians, CPS requests the Board consider signing the MOU.

6. ***Maintain Patient Mobile Lifestyles and Consistent Pharmacy Access for Better Health Outcomes:***

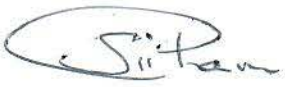
   Several technological advances have made today's modern world smaller than ever. People may live in one state, work in another, have bi-coastal living schedules, reside near state lines, or in states that lack numerous compounding pharmacy choices. Patients want to maintain consistent access to their prescriptions with the professionals and facilities they have developed a relationship. Health outcomes fare better when a patient's healthcare team is consistent. Not signing the MOU will discourage continuity of care for many patients, which may negatively affect their health outcomes.

For the reasons stated above, CPS urgently believes that patients and prescribers residing both outside and within California would prefer and benefit from having continued access to compounds produced and dispensed to them from California pharmacies. To test our belief, on April 5, 2021, CPS distributed a petition to patients and providers throughout the 48 states it serves, to ask the California Board of Pharmacy to sign the MOU. Within 10 days, CPS received an overwhelmingly positive response for California to sign the MOU. Specifically, CPS received 1,682 signatures from patients and providers outside of California and 1,053 signatures from those residing within California. We expect this number to grow as time goes by.

CPS realizes there is no easy answer in solving this problem and wants to help the Board find a resolution to this matter. One option for funding the reporting task would be to raise the sterile compounding license fee and instill reinspection fees on facilities that are not compliant with regulations and that prompt additional inspections. Another option would be to model the reporting system after the product reporting systems and adverse event reporting systems imposed on 503Bs and pharmaceutical manufacturers by the FDA.

Thank you for your consideration. We invite the Board at its preference to discuss with us further, and look forward to participating in all future conversations regarding this matter.

Respectfully,



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