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Debra L. Billingsley, Executive Secretary

Sam Brownback, Governor

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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Proposed Memorandum of Understanding with the
Kansas Board of Pharmacy

Dear Madam or Sir:

The Kansas Board of Pharmacy (“Board”) would like to submit the following comments regarding the *Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products between the State of [Kansas] and the U.S. Food and Drug Administration* (“MOU”).

1. Under Kansas law, a state agency like the Board has only the authority granted to it by the Kansas Legislature. There is a real question whether the Board currently has the authority to perform functions on behalf of the U.S. Food and Drug Administration (“FDA”) as described in the MOU and/or assume the potential liability that may go with them.

2. Section III a.1. requires “[a]ppropriate agencies. . .[to] investigate complaints. . .”. Even if the Board could legally bind itself to perform these investigations, it could not investigate any licensee or entity it does not license or register.

3. Section III a.3. requires the Board to perform investigations that include “(1) determination of whether there is a potential public health risk or safety concern associated with the compounded human drug product; and (2) confirmation that any risk or safety concern associated with the product is adequately contained.” The Board has a limited number of Investigators available to it. Those Inspectors currently have full case loads. The Board has no current ability to hire additional Inspectors. Additionally, if the determinations quoted above involve anything more than determining whether a violation of the Kansas Pharmacy Law exists, the Board has no current ability to provide its Inspectors additional technical training. Further, there is again concern regarding whether the Legislature has given the Board authority to make these kinds of determination.

4. Section III b.1. would require the Board’s Inspectors to “review compounding records during inspections of compounding pharmacies to identify whether the compounding

pharmacy. . .is distributing inordinate amounts of compounded human drug products interstate.” As mentioned previously, the Board has a limited number of Inspectors all with full case loads. The Board has no current ability to add Inspectors. The Board has been advised by one compounding pharmacy that its software will not track out of state sales. In addition, the Board has no current authority to require compounding pharmacies to track the number of interstate sales. In a situation like that, the Board’s Inspector may be required to search the pharmacy records by hand—an unreasonably time consuming task, which may not be able to be performed with the existing staff of Inspectors.

5. Section III b.3. would require the Board to “take [disciplinary] action regarding any pharmacy, pharmacist. . .that distributes inordinate amounts of compounded human drug products interstate. As noted above, Kansas law limits the Board to perform only those functions it is authorized to perform by the Kansas Legislature. That same rule of law limits the Board to disciplining pharmacies for only those reasons identified by the Legislature. There is nothing in the Kansas Pharmacy Law that authorizes the Board to discipline a pharmacy for distributing “an inordinate amount of compounded human drug products.” As the term “inordinate amount” is defined in Section III b.4. of the MOU.

6. Section III b.4. of the MOU does not indicate over what period of time the determination of distributing an inordinate amount of human drug products is to be determined or how far back the Board must look to make the determination.

7. The Board would also adopt and incorporate the comments made by the National Association of Boards of Pharmacy.

Thank you for your consideration.

Sincerely,



Debra L. Billingsley
Executive Secretary