DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB−2890/P1dn
TKK:jld:jf

September 15, 2011

Senator Zipperer:

This bill provides immunity from liability for certain manufacturers and sellers of drugs and devices under certain circumstances. Please review the bill carefully to ensure that it accomplishes your intent and let me know if you wish to make any changes. I have the following questions about the definitions provided for this bill:

1. The drafting instructions provided definitions for "entity" and "research and development." However, because these terms appear only in the definitions, I did not create separate definitions for the terms but instead incorporated the definitional language within the definition for "manufacturer or seller." Okay?

2. "Entity" is defined to include an "individual ... having its United States corporate headquarters in Wisconsin [and] employing more than 200 residents..." Do individuals have corporate headquarters or employ more than 200 residents without forming some sort of business entity within which to operate? Is it your intent that the term, individual, be modified by the material that follows? Or should the word individual be removed from the definition? Also note that the use of the term "individual" without the modifying material could raise other issues related to the illegal manufacturing, selling, or distribution of labeled drugs or devices.

Also, is it appropriate to refer to the headquarters of a partnership or association as a corporate headquarters?

3. Do you wish to provide definitions for "device" or "drug"? See, for example, the definition for "device" and "drug" at s. 450.01 (6) and (10), respectively. Also, the drafting instructions refer to both devices and medical devices. To avoid confusion, I recommend selecting one term and using it consistently throughout the bill. Also, the broad term, product is used several times. Is that intentional? That is, would there be a reason to distinguish between drugs, devices, and products in this statutory section governing immunity for drug and device manufacturers or sellers?

4. The definition provided for manufacturer or seller, when read together with the definition for entity, does not specify that the manufacturer or seller is engaged in the manufacture, distribution, or sale of drugs or devices legitimately or with the approval of the federal Food and Drug Administration. See, for comparison purposes, the

definition for “manufacturer” at s. 450.01 (12). Do you wish to modify the definition for “manufacturer or seller” to address this point?

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