



State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING



Tommy G. Thompson
Governor

Marlene A. Cummings
Secretary

6 4 4 8 '98 SEP 21 P2:14

September 10, 1998

1400 E. WASHINGTON AVENUE
P.O. BOX 8935
MADISON, WISCONSIN 53708-8935
E-Mail: dorl@mail.state.wi.us
(608) 266-2112
FAX#: (608) 267-0644

Jane Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike Room 6027
Rockville, MD 20852

RE: Memorandum of Understanding with States under Section 127 of the Food and Drug Administration Modernization Act

Dear Ms. Axelrad:

The Wisconsin Pharmacy Examining Board has requested that I contact you regarding the requirement under the Food and Drug Administration Modernization Act ("FDAMA") that the Food and Drug Administration ("FDA"), in conjunction with the National Association of Boards of Pharmacy ("NABP"), develop a standard memorandum of understanding ("MOU"), regarding the compounding of drugs. This correspondence is sent on behalf the board in my capacity as its legal counsel.

Under the FDAMA, generally stated, we understand that a pharmacy that compounds drugs in Wisconsin and dispenses them into other states to an extent greater than 5% of total prescription orders dispensed by the pharmacy, will be required to obtain a manufacturer's license from the FDA unless Wisconsin has entered in the standard MOU to be developed by the FDA and NASBA. We also understand this provision will be effective on November 21, 1998.

The purpose of this letter is to place this board's voice along side others, such as South Carolina, in requesting expeditious development and dissemination to the states of a standard MOU. The board understands that there are other time-sensitive mandates placed upon the FDA under the FDAMA. This board has experienced similar problems in the past.

However, the board is aware of at least one pharmacy in this state that dispenses in excess of 5% of its product to other states that strongly advises the board it will be severely damaged economically if the standard MOU is not in place by the effective date of the FDAMA. The result is likely to be the pharmacy's relocation to another state that has entered into the standard MOU or, if no standard MOU is available in any state, the pharmacy has indicated the result would be "catastrophic", as it would likely have to cease its out-of-state dispensing practice all together.

98D-0272

C6

Jane Axelrad
September 10, 1998
Page 2

As you know, either result would be totally inconsistent with good public policy, consumer protection, and the intent of the FDAMA, itself. Obviously, Congress recognized that the compounding and dissemination of compounded drug products by pharmacies is appropriate, and indeed, necessary to the public health, safety and welfare. It also recognized that as long as the interstate commerce in these products are effectively regulated by the FDA, in conjunction with standard agreements entered into with each state, pharmacies that provide such services must be permitted to do so without the necessity of obtaining a manufacturer's license from the FDA.

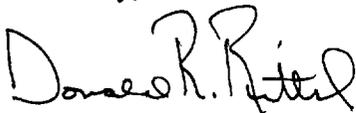
Accordingly, the Wisconsin Pharmacy Examining Board requests that a standard MOU be developed as quickly as possible for its and other states' consideration.

At the same time, it is requested that you recognize that not all states, including this one, are in a position to adopt any MOU on very short notice. In Wisconsin, for example, the board does not meet every day; but rather, once every month. Accordingly, as of this time there are only two scheduled board meetings prior to November 21, 1998. Even if a standard MOU were available for the board's review today, this factor provides precious little, if any, time to not only consider, but to undertake any steps necessary for it to resolve and implement procedural and staffing matters necessary to comply with a standard MOU.

Under these circumstances, which we do not believe to be unique to Wisconsin, it is strongly urged that the FDA formally indicate that will not engage in enforcement actions under this provision of the FDAMA until every state has had an adequate opportunity to review and determine whether or not to enter into the standard MOU once it is developed.

Thank you for your consideration of this correspondence.

Sincerely,



Donald R. Rittel, Attorney
Office of Board Legal Services
(608) 267-7217

cc: Wisconsin Pharmacy Examining Board
National Association of Boards of Pharmacy
Attorney Mary H. Michal

drr:i:peb/ltr/fdamou