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1317 '98 SEP 11 P1:14

August 27, 1998

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

Dear Ms. Axelrad:

Re: Memorandum of Understanding
with State Boards of Pharmacy
under FDAMA

On behalf of Madison Pharmacy Associates, Inc., a Wisconsin pharmacy that specializes in compounding drug products, I am writing to request that the Food and Drug Administration ("FDA") enter into a memorandum of understanding ("MOU") regarding the compounding of drugs with the Wisconsin Board of Pharmacy pursuant to the Food and Drug Administration Modernization and Accountability Act of 1997 ("FDAMA"), codified at 503A of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 353a. If FDA is unable to enter into an MOU prior to November 21, 1998, the effective date of this legislation, we request a formal assurance that FDA will delay enforcement of this statute until after a sample MOU has been issued and states have had a chance to enter into the MOU with FDA.

Madison Pharmacy Associates is a specialty mail-order pharmacy that compounds hormonal drug products for individual patients pursuant to a prescription from the patient's physician. These drugs are specifically tailored to the patient's own hormonal levels. Many of these prescriptions are prepared for and dispensed to patients in other states and are subject to the dispensing laws in those states.

The FDAMA provision requires that a drug product may be compounded if, inter alia, the drug product is compounded in a state

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that has entered into a memorandum of understanding with the Secretary [of the U.S. Department of Health and Human Services] which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State. 21 U.S.C. § 353a(b)(3)(B)(i).

FDAMA also requires FDA to develop a standard MOU in consultation with the National Association of Boards of Pharmacy for use by the states. 21 U.S.C. § 353a(b)(3).

Under the statute, if Wisconsin does not enter into an MOU, pharmacies in Wisconsin would be allowed to compound only five percent of their prescriptions for out-of-state patients. See 21 U.S.C. § 353a(b)(3)(B)(ii). This limitation is contrary to good pharmacy practice, since pharmacies that compound on a regular basis and which provide this service as a large portion of their business will generally have more knowledge, skill and experience compounding than pharmacies that compound less frequently. Therefore, it is crucial both from a patient safety perspective and for Madison Pharmacy Associates' business, that FDA enters into an MOU with Wisconsin.

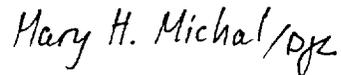
If an MOU is not implemented by November 21, 1998, our understanding is that Madison Pharmacy Associates will only be allowed to provide five percent of its prescriptions to out-of-state patients. Because Madison Pharmacy Associates dispenses many prescriptions to out-of-state patients, such a limitation would have a catastrophic effect on its business, which could necessitate moving its operations to a state that has entered into an MOU with FDA, if any exist by the effective date. Such a course of action is probably prohibitively expensive for this small business. If no other state has entered into an MOU, then Madison Pharmacy Associates would have to cease its out-of-state dispensing or risk criminal enforcement action against it by FDA.

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While we realize that FDA has numerous mandates from Congress that must be fulfilled under FDAMA, we are requesting at a minimum that FDA immediately issue a model MOU so that states such as Wisconsin can enter into an MOU with FDA prior to the effective date. If FDA determines that an MOU cannot be issued and/or that it does not have the staff to enter into MOUs with each of the fifty states prior to November 21, 1998, we ask that you issue a formal guidance that compounding pharmacies will not have enforcement actions taken against them while the MOU process is still pending.

To assist the FDA in developing and executing an MOU with the National Association of Boards of Pharmacy and/or the Wisconsin Board of Pharmacy, we are attaching a proposed draft MOU for FDA's consideration.

Sincerely yours,

Handwritten signature of Mary H. Michal in cursive script.

Mary H. Michal

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Enc.

cc Donna Shalala, Secretary of the Department of Health and Human Services
Senator Herbert Kohl
Senator Russell Feingold
National Association of Boards of Pharmacy
Wisconsin Board of Pharmacy

MEMORANDUM OF UNDERSTANDING

I. Introduction

The purpose of this Memorandum of Understanding (“MOU”) is to protect public health by providing certain guidelines regarding the dispensing of and investigation of complaints relating to compounded drug products.

This MOU has been developed to comply with the elements of Section 127 of the Food and Drug Modernization Act of 1997, codified at § 503A(b)(3)(B)(i) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 353a(b)(3)(B)(i).

II. Investigation of Complaints Regarding
Compounded Drugs Shipped Interstate

A. The Wisconsin Pharmacy Board (“Wisconsin”) agrees to investigate complaints regarding compounded drugs received by Wisconsin whenever the compounded drug(s) originated from a pharmacy located in Wisconsin, regardless of the state in which the drug was dispensed to a patient.

B. If the complaint involves a death or serious injury of the patient, Wisconsin agrees to cooperate with Boards of Pharmacy in other states whenever such cooperation is requested

C. If Wisconsin receives a complaint about a drug that was compounded in another state, Wisconsin agrees that whenever it deems appropriate, it will seek the assistance of the Board of Pharmacy of the other state.

D. Wisconsin agrees that if a complaint about a compounded drug involves a death or serious injury, the Board of Pharmacy of either the state to which the compounded drug(s) was shipped or the state where the compounding pharmacy is located may initiate the investigation.

III. Inordinate Interstate
Distribution of Compounded Drugs

A. Wisconsin pharmacies may dispense compounded drugs interstate in an amount greater than 5% of total drugs dispensed or distributed provided that they notify Wisconsin and provide all information that may be required.

B. Wisconsin pharmacies that dispense more than 50% of their total compounded prescriptions interstate will be required to provide counseling to patients during regular business hours, but not less than 36 hours and five days a week, as well as a toll free telephone number which shall be affixed to the label of the patient's medication.

C. Wisconsin agrees to develop procedures to implement this section of this MOU.

IV. Compounded Drugs for
Office Use By Physicians

A Wisconsin licensed pharmacy may compound drugs for use by a licensed prescriber who administers or dispenses drugs, in accordance with state law, to patients in the prescriber's office. However, a pharmacy may not dispense compounded drugs to a prescriber for office use for the purpose of resale. The compounded drug(s) dispensed by the licensed prescriber must be prepared pursuant to an order by the licensed prescriber.