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18 March 1999

Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

To Whom It May Concern:

I am writing to oppose in the strongest possible way the proposal to prevent compounding pharmacies from shipping prescriptions to customers out of state.

A year ago I became very sick. I saw saw numerous doctors and was even hospitalized for 5 days. My insurance company and I spent over $10,000. No doctor could come up with a diagnosis. Eventually, a hormonal problem was suspected. I had been quite sick for 4 months, including losing 25 pounds, when a well-meaning ob/gyn prescribed Premarin for me. He was sure it would "do the trick." After two weeks, I was sicker than ever and also suicidal. I managed to persuade him to prescribe some natural progesterone, which alleviated the worst symptoms. Then a friend told me about a compounding pharmacy. It is not an exagerration to say that the compounding pharmacy may have saved my life. By telephone consultation, they were able to suggest natural progesterone and natural estrogen, in very different proportions from my previous prescription, based on my symptoms. Over the next two months, I gradually got well.

I found two main advantages to the natural hormone treatment. First, separating the two hormones, rather than taking them together in fixed proportions determined by manufacturers, made it possible for me and my physician to titrate the dosages until my symptoms disappeared and I was well again. The proportions which I now take are not found in any standard prescription drug available. Second, I found I had adverse reactions to the synthetic hormones and equine hormones contained in standard hormone replacement prescriptions. I have no adverse reactions whatsoever to the natural hormones provided by the compounding pharmacy.

Two more points:

98N-1265 1. Although I live in the New York City area, I found it almost impossible to find a physician willing to spend any time helping me figure out what was wrong with my hormone balance and what the right supplementation regimen would be. This may be because it is quite time-consuming to listen to a patient's symptoms and follow up on a frequent basis until the right combination is found. Hormonal problems are C368

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not easily diagnosed by tests and there are no simple therapeutic dosages that work for all women at all times. It doesn't pay doctors to do this, and they don't do it.

The compounding pharmacies, however, make the treatment of hormonal imbalances their sole business. They have well-trained, professional, experienced, up-to-date telephone staff (registered nurses and pharmacists) and computer systems which enable them to consult with patients by phone, keep track of symptoms and dosages, and suggest adjustments which are beneficial to the patients.

If it is difficult to find a physician in the NYC area who wants to do the unremunerative, often frustrating work of re-balancing female hormones, it seems likely that women in more remote areas probably need this service even more. I can't understand what public purpose could possibly be served by limiting women's access to the best possible health care for their particular needs. I also feel that women's husbands and children, who depend on them for a normal family life, will be very badly served by this proposed curtailment.

2. I initially used a New York pharmacy for the natural progesterone I take. It involved going into New York City, as no pharmacy in my town was able to compound the required prescription, and the cost was DOUBLE that of the mail order pharmacy for the same product. In a nation which is very concerned about the rising cost of health care, it is impossible for me to see why a proposal has been made to put the interstate compounding pharmacies out of business.

In summary, both on humanitarian and economic grounds, I urge the FDA to abandon this draft MOU and allow women to continue to get specialized advice and individualized prescriptions from national compounding pharmacies. It is not simply the prescriptions, but also the accompanying professional advice, which enable women who would otherwise be sick, disabled, suicidal or worse, to live normal, healthy lives. As a voter and taxpayer, this is a goal which I assume the FDA supports wholeheartedly.

Very truly yours,

Kimberly Albright

cc: Nita Lowey, Representative, U18th Congressional District for the State of New York
Daniel P. Moynihan, Senator for the State of New York
Charles Schumer, Senator for the State of New York

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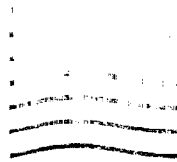

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