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July 25, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville, MD 20857-0003

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In it's present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer, there should be no restrictions to the delivery of compounded medication prescribed to me, regardless of where I live or travel. The MOU must be amended!

The FDA is an agency of the US Government that purports to be the watchdog for consumer safety. This is not a safety issue! As a governmental agency, the FDA also has a responsibility to be accountable to the people.

Personal comments:

I have suffered from a condition that, for many years, no doctor could seem to explain or to help me with until recently. Now that I am finally receiving the proper treatment for this thyroid condition in the form of a compounded medication - and achieving very positive results - the FDA is threatening to pull the rug out from under me, so to speak. Because compounding this medication is so specialized, my physician and I must rely on a compounding pharmacist from out-of-state to provide me with this medication. There is no local pharmacy that is able to do this. Please don't restrict my (and many others') ability to obtain vital medical treatment. Just imagine how you would feel if someone close to you were ill and were then denied medical treatment simply because their 'local' pharmacist was not familiar with the treatment protocol?

Sincerely,

Carol Pelkola

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