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1430 Forbes Street  
North Tonawanda,  
New York, 14120  
27 July 1999

Dockets Management Branch (HFA-305), 5 JUL 30 1999  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland, 20857-0003

Re: Docket No. 98N-1265

Dear Sirs:

I understand that the MOU, as written, severely limits the practice and interstate distribution of compounded drugs. The MOU places further unnecessary restrictions on consumer choices and commonly accepted professional pharmacy compounding practices. I believe that state agencies, pharmacists, doctors and healthcare consumers have expressed concern regarding this MOU.

Compounded drugs are often alternative solutions for individuals who have difficulty with or toxic reactions to patented or non-compounded drugs. My wife, in particular, has life-threatening reactions to any alternative form of progesterone which is NOT naturally compounded. Specialty pharmacies currently fill a unique niche in response to the increasing demand for custom-compounded drugs, such as those using NATURAL ingredients as an alternative to patented synthetics. EQUAL TREATMENT UNDER THE LAW IS CALLED FOR.

My wife at, at one time, was on the verge of cancer of the female organs. The progesterone provided by the Women's International Pharmacy has prevented drastic measures which the patented version would not. I implore you to reconsider the aforementioned docket so that her peace of mind and body are preserved.

Your consideration at this time is deeply appreciated.

Yours truly,  
*Michael P. di Pota*  
Michael P. di Pota

98N-1265

C5249

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