Docket # 98N-1265 From: [redacted] Wiseman
[redacted] Randall
[redacted] 3715

I'm writing to request that the MOU be amended no later than July 29, 1999! The MOU that the Food and Drug Administration as a part of the FDA Modernization Act of 1997, the FDA drafted Section 503A which governs the practice of pharmacy compounding. The Modernization Act does not accurately represent the original intent of congress. It places further unnecessary restrictions on consumer choices and commonly accepted pharmacy compounding practices. If the MOU is approved many consumers such as myself will no longer have access, which is sorely needed for my health, that are currently used as effective treatments. I have a dramatic [redacted] problem with low levels of Progesterone in my body. The pharmacy I use compounds natural Progesterone to assist me in getting my levels of Progesterone to normal state. Without this I suffer from crippling headaches, insomnia, depression, weight gain as well as other maladies. Without access to this personally compounded hormone my state of health would deteriorate rapidly. In essence the MOU places a "gag order" on pharmacists who specialize in compounded drugs which in turn hurts the patients,

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The MOU threatens the economic survival of specialty pharmacies, further restricting consumer choices! The specialty pharmacy I use, Womens International Pharmacy, uses natural ingredients to compound their prescriptions which there is an increasing demand for. I, myself am not helped at all by synthetic compounds as my body (and most bodies if not all) sees as a foreign matter and excretes. As a result I get no relief from my problem of hormone imbalance which can be crippling. If left untreated these imbalances can lead to greater problems affecting most of us (more than you may realize) who need the prescriptions to become sick enough to be rendered disabled. In the long run the government will end up paying for this by creating a population of people who are unable to work and eligible for disability.

I urge you to amend the MOU no later than July 9th, 1999. The Docket No. is 98N-1265 In its present form, the MOU as well as the compounding section 503A of the modernization act severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice and infringes on the rights of compounding pharmacists to serve the needs! Please do not restrict my right to choose medical as well as many others to a better quality of life. I urge you to put yourself in my shoes and consider how you would feel if your lack of access to the medication you needed to make your healthy was rendered unavailable! Pretty scary!

Sincerely, Shelli Willman

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14 JUL
1999

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RE: Docket No. 98N-1265