Alpine Women's Healthcare, P.C.
Obstetrics • Gynecology • Incontinence

Nancy L. Panter, M.D.
Nancy Germer, M.D.
Gretchen Frey, M.D.
Jayne L. Jones, C.N.M., M.S.N.
Lynne Parker, C.N.M., M.S.N.
Mary Beth Haas, R.N., C.N.P.
Claire Loughry, R.N., C.N.P.

499 E. Hampden Ave., Suite 350 • Englewood, Colorado 80113
(303) 744-3477 FAX (303) 733-5848

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Dear Sir or Madam:

My name is Gretchen Frey. I have been actively practicing obstetrics and gynecology since August 1989. Approximately ten years later, around 1999, I began prescribing compounded hormones for many of my menopausal patients. I have continued to use this route for many patients, as there are a number of individuals who are not well served by the commercially available hormone preparations. One example which comes readily to mind is the use of testosterone for decreased libido issues in ovariectomized women. As you know, there are testosterone preparations currently in clinical trials for transdermal use for this very diagnosis. Since there has not yet been an FDA approved testosterone preparation, I have been using compounded testosterone either in sublingual or transdermal form with good results in the patients who meet the indications for prescribing such.

I am in receipt of Wyeth's petition to the FDA which, to summarize, appears to request that the compounding of bio-identical hormone replacement therapies be disallowed. They give several appropriate arguments for doing this. However, while I am in agreement with some of their points, I am not as convinced about some of the others. I do agree that the compounding pharmacies need to be extremely responsible about disclosing risks of these hormones. I personally tell all of my patients that I cannot guarantee safety of these compounds. I tell them that there is good basic science evidence that they may prove to be safer, but I have no clinical studies to back up what is essentially my professional opinion. I think the compounding pharmacies should do at least as much. However, if the products are given with appropriate notification of risk, just as the labeling now requires for Premarin, I think it would be a shame to eliminate the option of compounded hormone prescriptions for these patients. With the availability of so many different routes of hormone administration, I have been able to help many more patients than I could have with only the commercially available hormone replacement therapies.

To conclude, the benefit of compounded bio-identical hormone replacement therapy is that it can be highly individualized for those who do not tolerate or respond well to commercially available hormone replacement therapies. In some cases such as the administering of testosterone for decreased sexual desire disorder in ovariectomized women, bio-identical compounded hormone therapy is the only option for administering native testosterone. I am concerned that Wyeth's petition (Docket 2005 P0411) would limit my ability to keep prescribing these individualized medications for my patients. As a result, I think the FDA should carefully consider rejecting at least the most restrictive requests of this petition. I think the FDA should require compounding pharmacists to fully disclose risks of the compounded medications, which would be an improvement on the current situation.

Sincerely,

Gretchen Frey, M.D.

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