Case Reports

**Natural HRT: Hysterectomy No Longer Necessary**
Kathy Jackson, R.Ph.
LaPorte, Texas

A 39-year-old woman presented with severe symptoms of premenstrual syndrome (PMS). In addition, she had fibroid tumors, severe bleeding, clotting menses, bladder pressure and urinary frequency. Her physician said her uterus was the size of a six-to-eight week pregnant woman’s. During her annual gynecological exam, her physician explained that she was a hysterectomy candidate and that she should start planning for the surgery the following year. The patient was opposed to having a hysterectomy and requested a prescription for natural hormone replacement therapy. The physician prescribed 50 mg of progesterone.

We compounded a 25-mg transdermal pluronic lecithin organogel (PLO) to be applied twice a day to the wrist and inner thigh, beginning midcycle (day 10-11) until the first day of menses. The patient tried this treatment for one month, with no or very little relief. The second month her prescription was increased to 50 mg twice a day, again beginning midcycle (the tenth or 11th day) to the first day of menses. Still her PMS persisted, as well as bladder pressure and urinary frequency.

Because her PMS was still severe, we recommended that her dosage be increased to 50 mg twice a day starting several days prior to ovulation (day 9) for about one week and then increasing after ovulation to 100 mg twice daily until menses. We prepared a 100 mg in ½-cc transdermal PLO for application to the wrist in the morning and inner thigh at night. The patient used one-fourth to one-half per dose, depending on the week of her cycle. Within six months the bladder pressure and urinary frequency were alleviated. The patient said the clotting was gone, which indicates a balance between progesterone and estrogen. The patient did complain of breast tenderness. We attributed this to increased sensitivity of the estrogen receptors due to the increased dosages.

After ten months of treatment at the increased dosages, the patient returned to her physician for her annual exam. He could not palpate any fibroids, and her uterus had shrunk to what he said was slightly above normal. The physician said that she is no longer a hysterectomy candidate.

We are currently working with the patient to reduce her dosages and hope that slow decreases in strength will not cause a recurrence of her symptoms.

**Compounded PLO Successful in Early Treatment of Herpes Zoster (Shingles)**
Gar Houck, R.Ph.
Clear Lake, IA

A 67-year-old woman presented with the early stages of herpes zoster (shingles), concentrated across her mid driff and lower back. She complained of pain so excruciating that it prevented her from sleeping. She had received a prescription from her physician for a five-day treatment of hydrocodone/acetaminophen (Lortab) 7.5 mg for the pain and valacyclovir hydrochloride (Valtrex ®) 500 mg for the herpes. I filled the prescription but suggested that, if she did not experience relief within five days, to come back so that we could discuss some treatment options with her physician.

Within three days the patient returned to the pharmacy with little to no relief. She was still unable to sleep due to the pain. I consulted with her physician and pre-
pared a 20% pluronic lecithin organo-
gel (PLO) with deoxy-D-glucose 0.19%, 
ibuprofen 10%, lidocaine 5%, baclofen 2 
mg, and amitriptyline 2%. I was very 
specific in my instructions to the patient 
to apply a small amount the size of a garden 
pea to the affected areas and massage in 
throughly only to the diameter of a dime. I told her to apply the PLO to the site where 
the pain was the worst. I was afraid she 
would take a small amount and rub it over 
a large area of her body and not get strong 
enough concentrations on the most severely 
affected areas.

The patient reported back to me in 24 
hours and said the pain had been allevi-
ated enough to allow her to sleep. I re-
ferred the prescription last night because 
time and she reported that the shingles 
was gone after 21 days of the treatment.

Lawrence Summary

In Vivo Study Shows Progesterone May Prevent Breast Epithelial Hyperplasia

Source Chang, KJ, Lee, TTY, Linarez-Cruz, G, 
Fontes-Serrano, S, de Lignieres, B, Influences of 
percutaneous administration of estradiol and 
progesterone on human breast epithelial 
cell cycle in vivo. Fertility and Sterility 

Results of this double-blind, randomized, 
in vivo study, strongly supports the con-
cept that physiologic secretion of progest-
ereone during a normal luteal phase favor-
ably influences control of the human breast 
epithelial cell cycle. This study of pre-
menopausal women also suggests that 
progesterone or related hormones may have a 
therapeutic value in preventing breast epithelial hyperplasia when used 
ten to 13 days per month at appropriate 
subtherapeutic doses.

Today critical decisions about 
progesterone’s influence on normal epithelial 
breast cells are based on insufficient 
and conflicting data. While it is generally 
recognized that estradiol, even at 
physiological concentrations, increases the 
mitotic activity of epithelial cells, the 
role of progesterone continues to be de-
bated. Past studies have called for restric-
tions of progestogens or their widespread 
use. In vitro studies have shown that 
progesterone decreases the mitotic activ-
ity of normal human breast epithelial cells and 
partially inhibits the estradiol-induced 
growth response in most human cancer-
ous cells. Therefore, the findings of a 1985 study 1 suggesting 
that piracetam can increase the rate of 
reading in dyslexic children 12 years of age 
and had average intelligence and similar 
reading quotients; Both groups were com-
parable at baseline with respect to height, 
weight, race, verbal IQ, performance IQ, 
peer-education opportunity, and current 
emotional status.

Patients randomly received either a pla-
cbo or a solution containing 0.3 g of piracetam 
and dibhydroxysteine, 3 g of deoxy-D-glucose 
twice a day, for a total of 3.3 g of piracetam 
daily. Piracetam was well tolerated, and no 
serious or unusual adverse reactions were 
reported.

The results of the present study extend 
the findings of a 1985 study 1 suggesting 
that piracetam can increase the rate of 
reading in dyslexic children.

Legal Brief

Compounding Law: Understanding New Legislation

(Fourth of Six Articles)

Section 503(A) of the Food and Drug Administration Modernization Act of 1997 
(FDAMA) sets forth six basic parameters for the practice of compounding. If phar-
macists comply with these parameters, the law 
exempts them from the Food and Drug
Administration’s New Drug Applications (NDA) and Good Manufacturing Practices (GMP).

The new law prohibits a pharmacist from advertising and promoting the com-
pounding of any specific drug, class of 
drug, or type of drug. However, the law 
allows for the advertising of compounding services. The pharmacist may advertise the 
sermaceuticals that compounding services are provided by the pharmacy but may 
not advertise a list of drugs that the pharmacy compounds.

Prescriber Q & A

Jeffrey N. Gibbs, Esq.

Q: As a dentist, I wanted to receive a list of all products that the local pharmacist compounding pharmacy. The pharmacist said providing such a list would make him legally vulnerable. How can I learn what compounded medica-
tions are available for my patients?

A: Under the new pharmacy provisions, a pharmacist cannot advertise or promote specific compounded products if he or she wants to remain exempt from the Food and Drug Administration’s NDA and GMP requirements, the GMPs, and the need for full 
product labeling. Providing an unsolicited list of compounded products to a practitio-
n would void this exemption. The pharmacist needs a list of products that can be 
compounded, he or she can request a list in writing. The pharmacy can also 
provide the list in response to an oral, unsolicited request. In that case, the 
pharmacy should send a cover letter confirming that the list is being sent in response to the practitioner’s unsolicited request. A document showing that the list is 
prepared by the practitioner will maintain the ex-
emption.

One of the main purposes of the legisla-
tion is to distinguish between drug manu-
facturers and compounding pharmacies. The advertising and promotion provision of 
the law was included to delineate this distinction. Drug manufacturers make and 
distribute pharmaceuticals for mass con-
sumption. Commercially available products are subject to the NDA requirements, as 
well as the GMPs. By meeting these re-
quirements, manufacturers can advertise 
and promote products directly to pa-
tients and physicians.

Compounded medications are not subject to the NDA requirements or the GMPs. Congress concluded that because these 
products are compounded to fill prescrip-
tions, rather than to be mass-marketed, they 
cannot be advertised or promoted and still 
bet be exempted.

The constitutionality of these restrictions has been challenged by a group of phar-
macists. They were successful in obtain-
ing a temporary restraining order prohib-
iting the FDA from enforcing the antipromotion/advertising provision of the 
law. The court will now have to decide whether to issue a preliminary or perma-
nent injunction against the FDA’s enforce-
ment of the ban on advertising.

Under the court’s order, pharmacies can, 
as of this writing, provide product lists to practitioners. However, if the perma-
nent injunction is not imposed, the statute will be 
effect in again; and the FDA will be able to 
are pharmacies that refuse their exemp-
tion by advertising and promoting. Thus, 
if a pharmacy wants to play it safe, until the 
legal situation is clarified it should 
continue to document that the product 
list was provided only in response to un-
solicited requests.

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