



Specialty Medicine Compounding Pharmacy

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# Competent Compounding

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## Compounding Pharmacy Wins Legal Battle

The International Academy of Compounding Pharmacists today applauded the ruling from U.S. District Court Judge Robert Junell that compounding is legal. The Court's written opinion follows an initial ruling from the bench issued on May 25, 2006.

"The Court's ruling is a precedent-setting victory for millions of patients, their doctors who prescribe compounded medicines for them and the compounding pharmacists who prepare their medications," said L.D. King, executive director of IACP. "Congress, the U.S. Supreme Court, and each of the 50 state boards of pharmacy that regulate compounding have long recognized the value of pharmacy compounding, yet the FDA has contended for nearly 20 years that compounded medications are illegal. This ruling affirms what the rest of the government and medical establishment have long held – compounding is vital and it is legal."

The case – Medical Center Pharmacy, *et al.* v. Gonzalez, *et al.*, No. MO-04-CV-130, in the United States District Court for the Western District of Texas, Midland-Odessa Division – was filed in September 2004 by 10 pharmacies against the Food and Drug Administration and addressed a number of issues affecting the practice of pharmacy compounding.

First, the Court ruled that "compounded drugs do not fall under the new drug definitions" and, as a result, are legal. Judge Junell explained: "If compounded drugs were required to undergo the new drug approval process, the result would be that patients needing individually tailored prescriptions would not be able to receive the necessary medication due to the cost and time associated with obtaining approval. ... It is in the best interest of public health to recognize an exemption for compounded drugs that are created based on a prescription written for an individual patient by a licensed practitioner."

Second, the Court ruled that pharmacies are exempt from the requirement to submit to an FDA inspection of their records unless FDA can demonstrate that the pharmacy is not compliant with applicable state laws and does not operate as a retail pharmacy. The Court also ruled that each of the 10 plaintiffs met the requirements for exemption.

Third, the Court ruled that compounding from bulk pharmaceutical ingredients for non-food animals is legal. This is an important issue for animal owners and their veterinarians who prescribe compounded medications to treat a variety of conditions, many of which require medications that are only available by compounding bulk pharmaceutical ingredients. Without them, animals may needlessly suffer or even die. Until now, FDA asserted that prescribing and preparing these treatments was illegal.

## Q & A With Kenny Walkup, RPh

### Q: What interested you in working with women and bio-identical hormone replacement therapy (BHRT)?

A: When I first started training for a career in pharmacy compounding I truly did not know what to expect. I knew I liked compounding but did not know what I would be compounding. After I opened my pharmacy the very first prescription I received was a BHRT script for an estrogen product. After researching how to compound the product and its uses I became fascinated with the prospect of making BHRT a main-stay of my practice. Numerous conventions and training sessions have given me great confidence in working with men and women. There is great satisfaction in helping solve the hormonal issues that we all face.





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## Veterinary Compounding Corner

Quack-Quack!

### Case Report: The Sick Duck

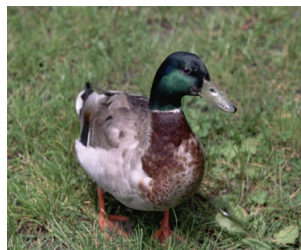


I love the challenge of working with all kinds of animals. We have made medicine for the smallest fish and turtles up to the larger breeds of horses. Each animal presents its own set of unique challenges.

One day a local veterinarian called me because a lady had been the recipient of a sick duck that had been dropped off in the pond in her yard. The duck had severe fungal and bacterial infections. I talked at length with the new owner and found out the duck only ate corn. So there was the challenge, get the medicine into the duck who only eats corn. After buying a can of cream corn at the grocery store, my staff pureed it and strained off the chunks of corn. We then used a thickening agent, some sweeteners and mixed the drugs into the corn suspension. I asked the owner to bring the duck into my pharmacy. After all, I wanted to see if the duck liked the corn shake that I had made (plus, I had never held a duck before). The duck did indeed like the corn shake and was able to take his medicine.

What challenging pet problem do you have?

Call me, I love to help out.



# Bellafemme

## New Product for Women Dealing with The Change of Life

*Bellafemme* Balance for Women is a new, all natural supplement designed to promote healthy phytoestrogen activity. Natural phytonutrients in this 100% muscadine grape skin blend work synergistically to alleviate hot flashes, mood swings, night sweats, and insomnia. These phytonutrients have also been scientifically studied as natural antioxidants and natural anti-inflammatory agents that target and neutralize a broad range of damaging free radicals within the body.\*

**Special introductory pricing through February 28**

You can buy *Bellafemme* now through February 28 for \$25.99 per bottle or three bottles for \$22.99 each. Please call the pharmacy toll free at 866-446-2643 to ask questions or place your order.

\* These statements have not been evaluated by the FDA. This

# Bellafemme

The demands of modern compounding have led to the creation of pharmacies devoted solely to this art. **Specialty Medicine Compounding Pharmacy** has been serving your community for over seven years. Here we spe-

cialize in bio-identical hormone replacement therapies and veterinary medicine, to name a few. We have all the facilities and equipment needed to make anything from topicals to capsules and sterile injectables. We do not ac-

cept insurance, but do provide claim forms with prescriptions we fill. So, next time a patient wants a compound you're unsure of - we'd be happy to serve them!

