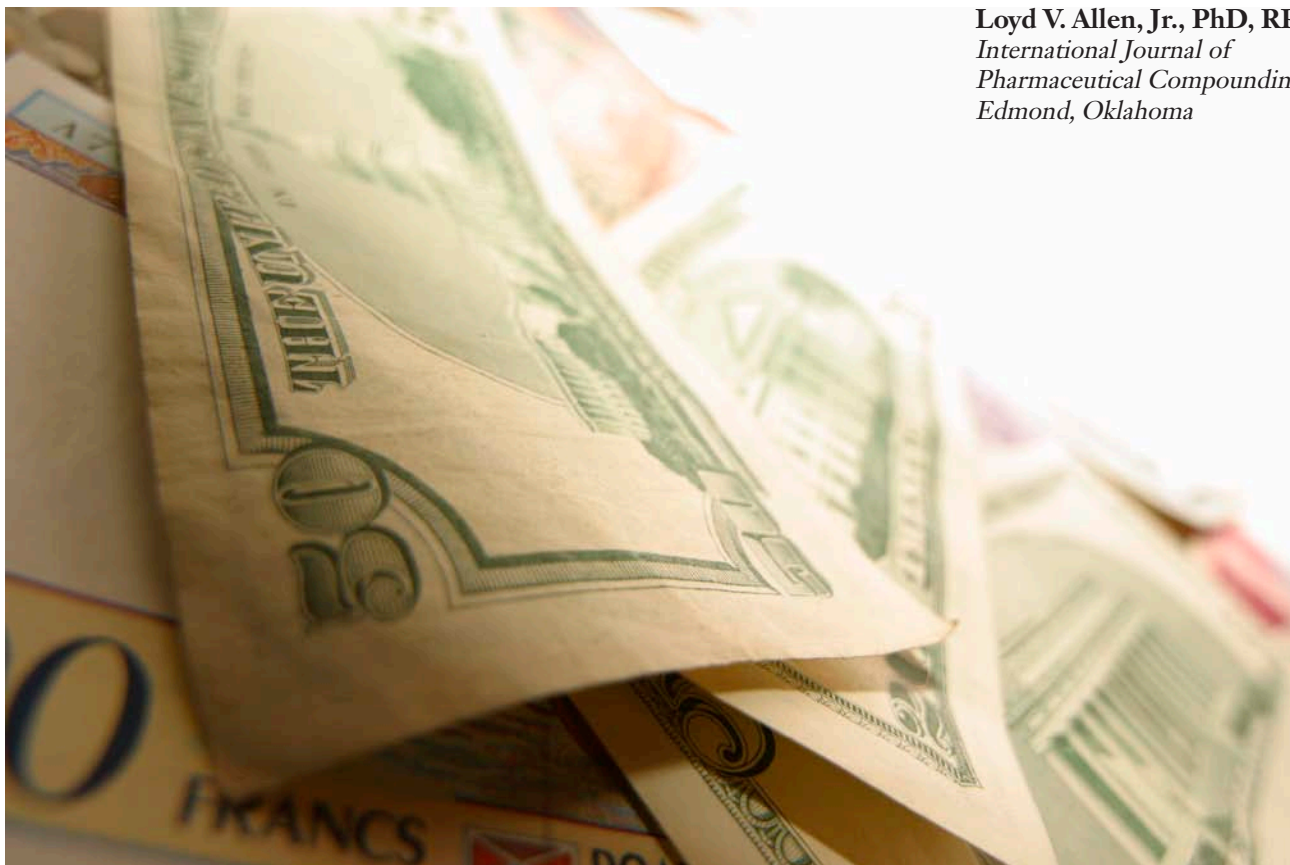


The Politics\$ of Hormone Replacement Therapy

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This issue of the International Journal of Pharmaceutical Compounding includes several articles about hormone replacement therapy. Some of those articles are similar in content, but they have an important message in common: Patients, physicians, and compounding pharmacists should not be swayed by the misconceptions about compounding prescriptions for patients requiring hormone replacement therapy, nor should they be influenced by misinformation about the profession of pharmaceutical compounding. The pharmaceutical industry drives and funds both the legislative control and minimization of pharmacy compounding and, by disseminating misinformation and presenting biased viewpoints, openly discourages compounding. Political activists are working for both sides—for the pharmaceutical industry and for the profession of compounding—and such politics will continue for many years.

Hormone replacement therapy (HRT) is a topic that has gained national and international prominence in recent years. More specifically, bioidentical hormone replacement therapy (BHRT) has been in the press and has been the topic of senate hearings. BHRT has caused major pharmaceutical companies to expend millions of dollars addressing the topic and influencing political decision making. It has resulted in letters to the U.S. Food and Drug Administration (FDA) and a flood of letters from patients receiving HRT concerning their medications. Why has this subject erupted in recent years?

As the pharmaceutical industry began making inroads into health care in the early and mid-1900s, pharmaceutical compounding declined as the drug companies, most of which were established by physicians and pharmacists, began manufacturing many drugs in many different dosage forms for many different groups of patients. Some of these were very successful, but some were not economical blockbusters. From the 1950s through the 1970s, the pharmaceutical industry did a good job of meeting the needs of patients, physicians, and pharmacists. Pharmacists were included in the promotional visits by "detail persons" (professional pharmaceutical service representatives), and the sales of manufactured medications increased. During the mid-1900s, a number of commercial products on the market contained bioidentical hormones (estradiol, progesterone, estriol, estrone, testosterone, etc.). Each of those hormones has had or currently has an official monograph in the *United States Pharmacopeia* (USP).

Conjugated estrogens entered the market in 1943. As a result of a massive promotional campaign over the years, nonhuman (i.e., nonbioidentical) hormones assumed a major share of the marketplace for patients treated with HRT. Even though bioidentical hormones were available, they did not compete with the highly marketed, patented, nonhuman hormones. Additional hormones were brought to the market through patent protection mechanisms, and such was the status of HRT during the 1970s and 1980s.

During the 1980s, pharmacy compounding began making its way back into mainstream health care. During this time period, the Pharmaceutical Research and Manufacturers Association (PHARMA) companies began merging and buying the smaller companies. When companies join together, they tend to look at all the products between the combined companies and determine which ones to keep and which ones to delete from their product line. The less-profitable products are often discontinued and no longer available from the manufacturer. The only way a physician and patient can access these drugs in many cases is to have them compounded. On Compounding-Today.com, the list of discontinued drugs has grown to over 8,000 products.

Insulin was once extracted from pigs and cows for use in humans, and thyroid supplements were originally obtained

from pigs. However, when human insulin, levothyroxine, and triiodothyroxine became commercially available, numerous bioidentical human hormones became replacements for hormone supplements once derived from animal sources. At that time, estrogens were already available on the U.S. market but had been replaced to some degree by other nonbioidentical hormones (e.g., conjugated estrogens extracted from the urine of pregnant mares). Many patients and physicians began requesting bioidentical human hormones compounded in dosage forms and doses that were not commercially available.

The word "bioidentical" is derived from the words "bios," meaning "life," and "identical," meaning "the same as." Therefore, "bioidentical" means "the same as life" or identical to what is in the living body, as opposed to synthetic substances such as conjugated hormones. In 2002, when the results of the World Health Initiative (WHI) study revealed the problems associated with the use of certain types of HRT, the sales of many of the most frequently prescribed synthetic hormone products plummeted. In an attempt to protect its market share, the pharmaceutical industry launched a great effort to downplay BHRT as a useless, ineffective, and po-

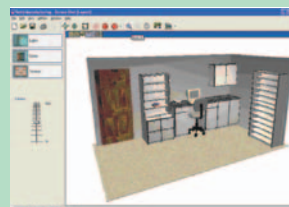
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tentially dangerous treatment. Large sums of money were provided to organizations, speakers, consultants, etc., who impugned the effectiveness and safety of BHRT. In addition, a letter about BHRT and compounding was submitted to the FDA. Was that letter written because the drug company that submitted it was concerned about patients? Obviously not, because when the letter in question was submitted to the FDA, its authoring company was under FDA investigation for:

Failure to thoroughly investigate the unexplained discrepancies or out of specification results of batches of Triphasil 21 and Triphasil 28 tablets manufactured at your site....¹

The letter from the FDA continues as follows,

It is noteworthy that our investigators have observed seventeen other examples, occurring between December 2003 and August 2005, where adequate investigations...were not performed.

These examples involved several different products that your firm manufactures including Ovrette, Zebeta, Alesse, Loette, Gestodene, Duofem, Velnafaxin, Rapamune, and LoGentrol.¹

The list of deficiencies noted in that letter continues, and the drug company was in no hurry to resolve those problems, a position that demonstrates a lack of concern for patients.

The drug company mentioned above must have been concerned about the loss of market share that followed the publication of the WHI report and responded to that loss by attempting to harm the business of compounding pharmacists via promulgating distortions and untruths about compounding to physicians, patients, the media, the public, and even the FDA. Some drug companies have even convinced major "professional" organizations to discourage compounding by passing resolutions at their national meetings. In addition, some of the organizations that obtain a significant amount of their financial support from the pharmaceutical industry also provide financial support to individual board members, officers, etc., under the guise of consultantships. How, then, can such organizations be unbiased? Obviously, they cannot be.

There has been and still is a big push by the pharmaceutical industry to support legislation that would control and minimize pharmacy compounding, which has been an essential part of health care since the earliest days of pharmacy, and benefits millions of patients every day. As an important part of today's health care, compounding supplies intravenous admixtures, parenteral nutrition solutions, pediatric preparations, and pain-management medications for patients whose medical needs would otherwise go unmet.

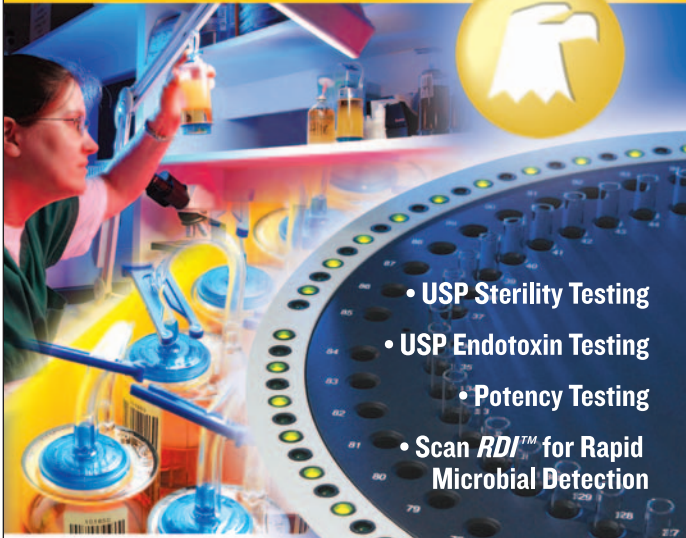
Questions about the efficacy of compounded medications often arise, but that issue can be put to rest, because compounded hormones are bioidentical to endogenous human hormones that are essential to maintaining good health. Pharmacists know that many substances in the human body (water, electrolytes [sodium, potassium, etc.], thyroid, pancreatic enzymes, and insulin) are used therapeutically to replace deficiencies that develop.

Bioidentical hormones are available in commercially manufactured (e.g., Prometrium, Estragel, AndroGel) and compounded forms. These have been recognized as safe and effective by the FDA. In addition, because bioidentical hormones are identical to those produced by the human body, they should also cause fewer adverse effects than do their synthetic equivalents if dosing is properly prescribed and the medication is correctly prepared and is used with compliance.

As the political fray involves the pharmaceutical industry, compounding pharmacists, Congress, the FDA, pharmaceutical associations, patients, and physicians, we must be cognizant of the following factors:

1. We cannot always believe information provided by the news media (television, radio, newspapers, etc.) Most of that information reflects the opinions and goals of its authors(s).
2. We must consider the money trail (industry, lobbyists, politicians' re-election campaigns, politicians' interests, Congressional bills, managed care, etc.)
3. A strong response by citizens can make a difference.
4. The pharmaceutical industry spends hundreds of millions of dollars in promotional and marketing activities; in fact, about 25% of each drug-industry dollar is spent for advertising or promotion (less is used to fund research). The news media are dependent on advertising dollars from the pharmaceutical industry.

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try (it would be difficult, if not impossible, to eliminate direct-to-consumer and other types of drug advertising). When that large-scale advertising is compared with the minimal advertising generated by compounding pharmacy organizations, a David and Goliath situation becomes apparent.

Conclusion

In summary, although the pharmaceutical industry promotes its products and discourages compounding by disseminating misinformation and biased views, pharmacists continue to compound and to meet the needs of physicians and individual patients. Political activists continue to work for both sides—for the pharmaceutical industry and for the profession of compounding. The political skirmish between pharmaceutical giants and individual compounding pharmacists is not over and will probably continue in some form or fashion for many years to come.

Reference

1. U.S. Food and Drug Administration. FDA Docket No. 2005P-0411. *Seeking FDA Actions to Counter Flagrant Violations of the Law by Pharmacies Compounding Bio-Identical Hormone Replacement Therapy Drugs*. [U.S. Food and Drug Administration. U.S. Department of Health and Human Services Website.] September 29, 2006. Available at: www.fda.gov. Accessed May 29, 2007.

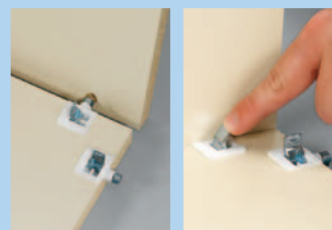
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