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Going Natural

Are “bio-identical” hormones better than synthetics for menopausal relief?

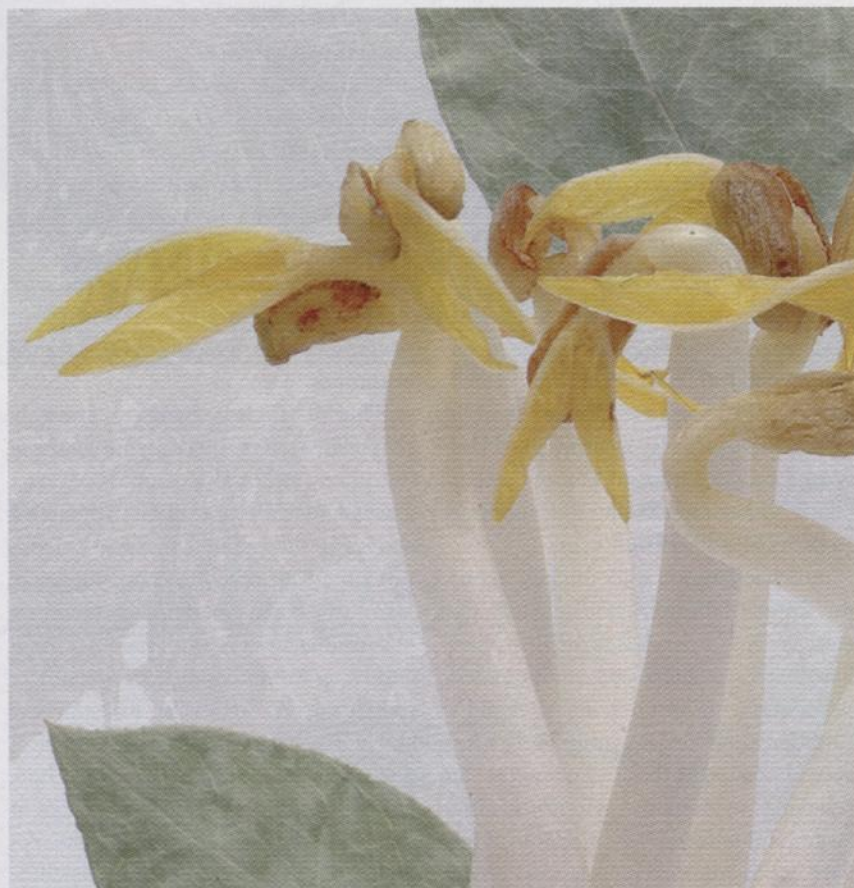
BY SUSAN LOVE, M.D., AND SUE ROCHMAN

IN 2002, THE NATIONAL INSTITUTES of Health dropped a bombshell: It abruptly halted its large Women’s Health Initiative study on hormone replacement therapy (HRT), having determined that the medication did more harm than good. The news left 15 million women in the United States, and countless others worldwide, wondering what to do next.

HRT had been billed as a virtual fountain of youth that would not only prevent hot flashes in menopausal women but also help keep hearts healthy, bones strong and minds sharp. Now it appeared that this hormonal youthfulness came at a price: an increased risk of breast cancer and heart disease. Virtually overnight, doctors went from routinely recommending HRT to suggesting women only use it if necessary to alleviate menopausal symptoms, then go off the regimen as quickly as possible.

Pharmaceutical companies saw sales drop and profits shrink as women stopped filling their HRT prescriptions. Millions of women decided to throw their estrogen away, dress in layers, carry a fan and hot flash away. Others, awash in uncomfortable menopausal symptoms, searched the Internet for alternatives, and what many found sounded perfect: compounded bio-identical hormones.

Bio-identical hormones are biochemically more similar to the hormones a premenopausal woman’s body makes than are the hormone therapies devel-



oped by pharmaceutical companies. Practitioners who recommend bio-identical hormones give women prescriptions to be filled by pharmacies that have the ability to create—“compound”—individualized doses. Typically, the practitioner determines which hormone to use and at what strength by conducting tests on a woman’s blood or saliva.

Practitioners who use these drugs,

▲ Bio-identical hormones are made from yam and soy (seen here as sprouts).

and the compounding pharmacies that make them, claim bio-identical hormones are better because their “natural”—rather than synthetic—ingredients are better absorbed by the body and produce fewer side effects. It is true that bio-identical hormones are natural, in that they’re plant-derived (from concen-

trated soy and yam). But that doesn't necessarily mean they are better than the drugs made by pharmaceutical companies. In fact, Premarin (estrogen alone) and Prempro (a combination of estrogen and progesterin) are made from pregnant mares' urine, which also comes from a natural source. (Whether it is right to harvest the urine is another question: PETA and other animal-rights activists are opposed to the practice.)

Practitioners who use bio-identical hormones say they have observational evidence of the drugs' benefits. But observational evidence isn't enough; after all, observational evidence got us into the whole HRT mess, as doctors observed that women who used HRT appeared to be healthier than women who did not. It was just as likely, however, that women who were healthier to begin with decided to use HRT, because they thought it would help them stay healthy. The NIH started its HRT trial to assess whether taking hormones really did improve women's health and well-being.

And just because something is "natural" does not mean it's safe, let alone effective. Only a handful of small studies have been conducted on compounded bio-identical hormones, and they indicate that these drugs are no more successful than synthetic hormones in relieving menopause symptoms. No large randomized trial—the gold standard of medical research—has been conducted with bio-identical hormones, and there have been no randomized trials comparing bio-identical hormones to a drug such as Prempro.

This means there is no evidence that bio-identicals are safer than synthetic drugs, or that they will cause fewer side effects. Furthermore, there is also no evidence to support blood or saliva testing as a means of determining the levels of hormones in a woman's individualized HRT cocktail.

No one even knows what a normal hormone level should be for a postmenopausal woman. As we approach menopause (our actual last period) our hormones fluctuate wildly, so a test might reflect what is happening in our bodies hormonally only at a particular moment—not two, four or 24 hours later.

Despite a lack of scientific evidence, sales of bio-identical hormones have increased as women skeptical of the pharmaceutical industry, or disposed to try alternative products, have sought substitutes for HRT. Their popularity was given a boost in 2004 with the publication of Suzanne Somers' bestselling book, *The Sexy Years—Discover the Hormone Connection* (Crown), which introduced millions to the little-known practice of compounded drugs and bio-identical hormones.

There is no way to know precisely how many women are using bio-identical hormones, although a recent *Wall Street Journal* article reported an estimate of about 2 million women in the U.S. Doctors and pharmaceutical companies have obviously taken notice: Last October, Wyeth Pharmaceuticals asked the Food and Drug Administration to investigate the "growing, unlawful manufacture and marketing of so-called 'bio-identical hormone replacement therapies.'" Later that month, the American College of Obstetricians and Gynecologists released a Committee Opinion concluding, "there is no scientific evidence to support claims of increased efficacy or safety for individualized estrogen or progesterone regimens."

A skeptic might suggest that pharmaceutical companies and physicians may be motivated by their concerns about losing business and profits—and she might not be wrong. However, that doesn't necessarily mean that bio-identical hormones are better or safer.

At the very least, the abrupt end to

NIH's hormone trial created a welcome opportunity to discuss the medicalization of menopause. It's still hard to erase from the cultural imagination the notion that menopause is a treatable "disease" resulting from "estrogen deficiency." In fact, menopause is not a deficiency state, and women don't return to premenopause by taking estrogen. The term HRT was a misnomer to begin with: Women don't need to have their hormones "replaced." Hormone levels are supposed to decrease as women age, and such a decrease is not a disease requiring treatment.

The real benefit of the bio-identical movement is that it has spearheaded a move away from the one-size-fits-all approach of recommending HRT to all women as they enter menopause. If you have severe hot flashes and are having a terrible time, short-term use of hormones—synthetic or natural—is fine. If you are taking a synthetic drug and it's not helping your symptoms, you can try a different formula. (Wyeth now makes low-dose pills, although there is no evidence that these are any safer.) You might also want to try a patch rather than a pill. And if you prefer using a product that is plant-derived rather than animal-derived, great.

Whatever you choose, don't take either bio-identical or synthetic hormones for more than three to five years. When you go off the regimen, taper slowly to help keep hot flashes from recurring. Getting through menopause is not a contest to see who can do it best. Ultimately, every woman arrives at the same place: the hot-flash-free phase of life as a postmenopausal woman. ■

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