What are bioidentical hormones?
The term “bioidentical” describes hormones that have the same molecular structure as hormones found in the human body. These include the hormones estrogen (estradiol, estriol and estrone), progesterone, testosterone, and DHEA. Drug companies and compounding pharmacies make these kinds of hormones from soy and yam extracts. They make pills, patches and creams. Synthetic hormones, on the other hand, do not have the same molecular structure as the hormones found in the body, but your body converts them into usable forms. Synthetic hormones can be made from various sources, including animal, soy and yam extracts.

Are bioidentical hormones safer than the synthetic versions?
No studies have proven that one form of hormone is safer than another. The Women’s Health Initiative Study looked at the synthetic hormones Premarin and Provera, and found some important risks associated with them. Those risks included:

- A small increase in blood clots.
- A small increase in risk for stroke in the women who started synthetic hormones in the first 10 years after menopause (50 to 60 years of age).
- An increased risk of breast cancer with synthetic hormones taken for more than 5 years.
- More heart attacks, strokes and dementia in women who started synthetic hormones at an older age.

It is tempting to say that the bioidentical hormones may be safer, but there is no evidence to support this claim.

Will hormone level testing help me and my physician or nurse practitioner decide which hormones I should take and in what dose?
Unfortunately, no. Your blood and saliva hormone levels change frequently (higher or lower). This makes the results almost worthless because it’s difficult to determine what they mean. Blood tests for estradiol, estrone, FSH and testosterone aren’t an effective way to evaluate menopausal symptoms. In fact, none of the tests are very accurate, and there is no information about whether there are safe or ideal levels. In addition, after menopause your hormone levels are uniformly low.

The only women who should take hormones are those with symptoms that are seriously affecting their quality of life, and who feel the benefits outweigh the risks. For most menopausal women, it is normal to have test results showing low estrogen, progesterone and testosterone. This does not mean that they need to take hormones. If you and your physician or nurse practitioner decide that the benefits of taking hormones are greater than the risks, you will be prescribed a low dose of hormones. The dose may be gradually increased as needed until your symptoms become tolerable. What is most important is how you feel; we always try to treat the woman, rather than focus on a test result.
If I am considering starting hormone therapy, should I get a “baseline” test of my hormones?
Baseline testing of estradiol, progesterone and testosterone is not necessary. The hormone levels have little or nothing to do with how you are feeling or which hormones you take. Since the results are not reliable and do not necessarily match up with your symptoms, the results do not change what we prescribe.

If I decide to take hormones, are there available products that have been scientifically studied and approved for use in women?
There are estradiol products (pills, creams, patches, gels and sprays) and progesterone pills and creams that are FDA-approved for use in improving menopausal hot flashes and related symptoms. These products are closely monitored for purity and consistency. The estradiol products currently available in Kaiser Permanente pharmacies include estradiol pills and patches in a variety of doses. We also have an estradiol cream and ring that are prescribed to treat vaginal dryness related to low estrogen levels. In addition, we can prescribe a micronized progesterone tablet. Both estradiol and micronized progesterone are considered bioidentical.

What do compounding pharmacies have to offer?
All prescriptions of estradiol and progesterone contain the same plant-based ingredients, regardless of whether they are filled at a compounding pharmacy or made by a pharmaceutical company. Compounding pharmacies fill a niche for hormones that are unavailable in a pre-packaged form in this country. Testosterone cream or gel, absorbed through the skin, is an example of a medication that is not currently available in the U.S. When it comes to estradiol, estrone, and progesterone, compounding pharmacies use the same plant extracts from yam and soy as in the FDA-approved products and mix them with creams and gels. They can customize the amount of hormones per dose and can vary the type of base, but this is the only difference between the compounded medications and those available from the pharmaceutical companies.

What is the downside of compounded hormones?
The FDA does not oversee or regulate compounding pharmacies. Therefore, we have serious concerns about the consistency from batch to batch and pharmacy to pharmacy. There is no government monitoring of purity, possible contamination, or accuracy of the prescriptions.

If I am taking estradiol, do I need to take progesterone as well?
If you have a uterus and are no longer having regular periods, we recommend that you take some type of progesterone along with any kind of estrogen that you apply to your skin (patches, creams, sprays, gels) or take in pill form. A low dose of estrogen cream placed into the vagina to help with dryness does not need progesterone to balance it (this is the only exception to the progesterone requirement). Use of estrogen alone can lead to an overgrowth of the uterine lining that can become cancerous. Progesterone in cream and gel forms has been studied and found NOT to protect the uterine lining. In order to prevent uterine cancer, a woman needs to take a progesterone tablet along with her estrogen.
What is estriol?
Estriol is a weak estrogen not available in any pre-made product in the U.S. When taken by mouth or in a cream its effects last a very short time. Studies have not found estriol to be safer than using small amounts of estradiol, or to have any other specific benefits. The FDA has reviewed the studies on estriol and found that it "has not been shown to be safe and effective for the uses for which it is being prescribed."

Is testosterone safe and effective?
There is very little research regarding testosterone use in menopausal women. Libido can be low for many reasons. Testosterone can be useful for some but definitely not all women with low libido. Concerns regarding testosterone include the risk of breast cancer and possible negative effects on the heart, blood vessels, and liver. In addition, increased facial hair and acne are common complaints. High amounts of testosterone can cause the hairline to recede, the voice to deepen and the clitoris to get significantly larger. A woman taking testosterone needs blood tests to be certain that the level is not too high.

Is DHEA safe?
The latest study on DHEA did not show that it improved well-being or libido in women. There is very little scientific evidence available, and we have serious concerns about the safety of DHEA. At this point, we do not know what, if any, dose is appropriate for use.

Summary
Menopause can be a difficult time for many women, and we understand and support your desire to alleviate the symptoms you may experience. Many things contribute to mood changes, irregularities in sleep patterns, decreases in libido and other conditions. Self-care through changes in diet, exercise, stress levels and other factors can make all the difference. Be sure that you are working with a well-informed, experienced doctor or nurse practitioner rather than relying on the advice of TV stars and businesspeople. Also, beware of expensive products and tests which have no scientific backing. If after reading this information, you have further questions:

- Consider attending one of our Menopause Classes. Contact your local Health Education Center or department to sign up for a class.
- Go to www.menopause.org, the site of the North American Menopause Society, which is a very comprehensive resource.
- Contact or make an appointment with your physician or nurse practitioner.

Other Resources
Visit your doctor’s home page at kp.org/mydoctor to view information about Women’s Health, use online health tools, view your Preventive Services reminders, check most lab results, and much more.

This information is not intended to diagnose health problems or to take the place of medical advice or care you receive from your physician or other health care professional. If you have additional questions, please consult with your doctor. If you have questions or need more information about your medication, please speak to your pharmacist. Kaiser Permanente does not endorse the medications or products mentioned. Any trade names listed are for easy identification only.