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Lessons from hormone therapy

"The desire to take medicine is perhaps the greatest feature which distinguishes man and animal."

— Sir William Osler, M.D. (1849-1919)

A FOLLOWUP study of the 2002 landmark Women's Health Initiative recently reported that women who took the combined estrogen and progestin therapy (HTR) faced a greater risk of being diagnosed, with not just breast cancer (24 percent greater risk) but all types of cancer, up to three years after they stop taking the hormones.

This latest finding adds fuel to a long history of heated discussions, since the 1970s, that have focused on the benefits and risks of promoting the use of hormone replacement therapy in healthy women. When both estrogen therapy (HT) and estrogen/progestin therapy (HRT) were introduced, the projected health benefits for middle aged and older women were highlighted and heavily promoted in both professional and lay journals.

We now know that the risks associated with hormone replacement therapy outweigh the benefits. Instead of preventing cardiac disease, use of hormone replacement therapy increases the risk of strokes, heart attacks and breast cancer. In human terms, the 8,506 women enrolled in the Women's Health Initiative treated with estrogen plus progestin had about 40 more coronary events, 40 more strokes, 80 more episodes of blood clots and 40 more invasive breast cancers than the 8,102 women given a placebo. Given the frequency with which HRT was prescribed to

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postmenopausal women worldwide, hundreds of healthy women have been harmed.

The story of hormone replacement therapy, a cautionary tale, is a call to action to re-evaluate the U.S. Food and Drug Administration's regulatory approval process.

There is not a drug that does not have side effects, yet, statistically, many of the side effects may not emerge until millions of people have used the drug for a period of time.

Why does it take years for dangerous side effects to become known? Part of the answer lies with the regulatory process. All new drugs are tested first on animals. If the results indicate that the drug is likely to be both safe and effective, the company applies to the FDA for permission to begin testing the drug on humans. Human studies have three phases: to evaluate safety, to determine effectiveness and to verify safety, dosage and effectiveness. Although a clinical trial may last up to five years and

include up to 10,000 participants that may not be a long enough period to determine either the safety or the effectiveness of the drug.

The current drug regulatory "rush to market" approach may make sense for drugs that are being developed to treat specific diseases since an earlier approval may actually save lives. However, drugs intended for or have a potential for being prescribed "off label" by physicians for use in healthy people should not be approved unless supported by the strongest evidence of benefit and virtually no evidence of risk. To do anything less is unethical.

Precautionary suggestions emerging from the story of hormone replacement therapy include:

▶ Exercise extreme caution when considering use of any hormone therapy whether synthetic or "natural."

▶ Chose drugs with a longer track record of safety and effectiveness, if you are making a choice between equally effective drugs. Being an "early adopter" of new drugs or new methods of administration is inherently risky.

▶ Weigh the risks and benefits of any drug. The greater the benefit, the more risk you may be willing to take. If your symptoms are mild or simply bothersome, you may decide the risk is too big and opt out of taking any medication.

▶ Maintain close surveillance of the side effects you may be experiencing and report them early and often to your physician.

▶ Maintain a healthy skepticism about the need for and proposed benefits of any medication.