

P & G poised to move on Intrinsa

'Passion patch' would deliver needed testosterone

By Cliff Peale

TESTOSTERONE FACTS

- Testosterone, estrogen and progesterone are the three primary sex hormones in a woman's body.
- The amount of testosterone in women is less than 10 percent of the amount found in men.
- The two main sources of female testosterone production are the ovaries and the adrenal glands.
- The testosterone level of women in their 40s typically is half that of women in their 20s. Surgery to remove a woman's ovaries also results in decreased testosterone production.
- Side effects of excessive testosterone in women can include deepening of the voice, acne or increased facial and body hair.
- Nearly 40 percent of women experience a decrease in libido during menopause.
- No testosterone therapy has been approved by the Food and Drug Administration to treat low sexual desire in women.

Source: P&G Pharmaceuticals

Enquirer staff writer

It's been decades since scientists formed the belief that testosterone therapy could spur increased sexual desire in women.

Now researchers think they have a reliable way to deliver the testosterone into the body and the profit model to make it work. One result is Procter & Gamble Co.'s Intrinsa, a patch that could be available by prescription as soon as early 2005.

Doctors expect Intrinsa, dubbed inside P&G as "the passion patch," to be the first of several such drug-delivery systems aimed toward increasing the sex drive of post-menopausal women.

"If it's a good patch and doesn't cause too much skin irritation, and if P&G gets it to market first, they're going to clean up," said Dr. John Adler, of Mount Auburn Ob-Gyn Associates. "There will be a huge demand."

The transparent oval patch must be worn on the abdomen and changed every three or four days. It sends enough testosterone through the skin and into a woman's bloodstream to restore the hormone to pre-menopausal levels.

The Food and Drug Administration is reviewing Intrinsa. A critical next step will come this week in Washington when an advisory committee of scientists will review clinical data and recommend an action to the agency.

P&G will present some of its clinical data, and interested groups - such as a California group called the Institute for the Advanced Study of Human Sexuality - will testify.

A recommendation by the committee to approve a drug often is regarded as a final step before FDA approval.

At stake is what Wall Street expects to be Procter's next blockbuster product. If it generates the \$1 billion or more in annual sales that P&G is hoping for, it will provide a growth engine in an entirely new category.

The venture into the sexual category is new for P&G, which has made its name for more than a century with staples such as detergent, toothpaste and diapers.

But it's aiming at a similar audience: Baby-boomer women who make decisions about purchases from shampoo to their own health care.

P&G is licensing Intrinsa and the technology from Watson Pharmaceuticals and hasn't set prices or labeling yet. But Intrinsa already has spawned international headlines about "female Viagra," referring to the erectile dysfunction drug made by Pfizer Inc.

The comparison makes Procter executives cringe. They hope to position Intrinsa as a serious medical treatment, not a Friday-night sex aid. They're interested in long-term therapy to treat sexual desire, not a short-term fix for sexual arousal.

But while it plays down such marketing buzz, P&G is firmly committed to the market.

"Women's health was an easy decision," chairman and chief executive A.G. Lafley said. "Sexual areas, we knew that would be controversial, and we decided to take it on in this case."

A medical problem

After nearly a decade of testing Intrinsa, the FDA application is to market it to women who have had their ovaries surgically removed. P&G also has trials going on to test Intrinsa with naturally menopausal women.

The target is at least 13 million American women who fit into one of those two categories and who suffer from low-sexual desire.

Procter researchers are going to great lengths to emphasize that a low libido level - known as hypoactive sexual desire disorder - is a serious medical condition, with testosterone therapy as a promising solution.

While competitors have talked of a \$100 million P&G marketing plan, P&G won't reveal the marketing budget and said it will concentrate on educating doctors and patients about the proper uses of testosterone therapy.

Dr. James Tursi, a medical director for Intrinsa at P&G's pharmaceutical unit in Mason, said he's convinced from his tenure in private practice that women can use testosterone therapy to treat real medical problems.

"I saw women every day who came in to complain about reduced libido," Tursi said. "One of the difficulties was we had nothing to give them."

Side effects? Once testosterone therapy products become available for prescription, P&G and other marketers will face head-on the issue of side effects. Increased levels of testosterone can cause deeper voices, acne or some facial hair in women, P&G acknowledges.

Tursi said the side effects occur only in a small number of women and are reversible if the treatment is stopped. He said that because of the controlled release and the fact that Intrinsa only restores pre-menopausal testosterone levels, incidences of side effects aren't significantly higher than in women taking a placebo.

A market opening P&G is not alone in its efforts to tap the female sexual dysfunction market. Another competitor, slightly behind P&G in its clinical-trial schedule, is Vivus Inc., a small pharmaceutical company based in California.

Like P&G, it has focused research on the delivery system and is testing a spray format. It also is testing another product to treat decreased sexual arousal in women.

Leland Wilson, president and chief executive officer at Vivus, acknowledges piggy-backing on P&G's marketing power. He predicted P&G would eventually market an entire family of Intrinsa products.

"The issue has always been one of timing in the marketplace," Wilson said, "and finding a business model that allows you to make money."