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FDA gives blessing to pill that halts male baldness

Associated Press

WASHINGTON – Millions of balding men are about to realize their dream of a pill to regrow hair: Once-a-day tablets will hit U.S. pharmacy shelves next month, but it may take lots of patience, and money, before men see results.

The U.S. Food and Drug Administration announced yesterday that it has approved Propecia, the first pill for male-pattern baldness, a potential way for men both to grow new hair and to stop existing strands from falling out.

"It's really an impressive drug," said Dr. Ken Washenik of New York University, who tested the pill on his patients and wound up taking experimental doses for his own baldness.

"People grew the kind of hair that relatives would notice. If you were home for the holidays, they'd say, 'What did you do to your

hair?'"

The FDA warned that women should never use Propecia because it can cause birth defects. Even for post-menopausal women, studies of safety and effectiveness are not complete.

For men, Propecia is not a miracle pill. About half who use it grow varying amounts of hair, and men may have to use it for six months to a year before they learn whether they're among the half that benefits, Dr. Washenik said.

Manufacturer Merck & Co. estimated each month's supply will cost \$45 to \$49.

But Dr. Washenik pointed to studies that show even if men don't regrow lots of hair, they may like Propecia: Only 17 per cent of balding men who took Propecia for two years were still losing their hair versus 72 per cent of men who took a placebo.

Propecia, which the FDA approved Friday

night, works by suppressing a hormone that shrinks hair follicles, thus causing hair loss.

It's a lower dose of a widely used drug called Proscar, known chemically as finasteride, that millions of men have taken to ease enlarged prostates. But because young men are expected to pop the new pill for many years, FDA scientists looked closely at side effects. The main problems were decreased libido and impotence, in just 2 per cent of men. The problems disappeared when they quit the drug.

Although Propecia can cause a certain birth defect in pregnant women – and doctors say they should not even touch the pills – Merck said it does not affect sperm.

To be safe, the FDA told Merck to continue studying Propecia patients who so far have tested the drug for two years, to see if problems emerge with longer use.

The article EM9706 reprinted above is used in Chapter 10 of the STAT 231 Course Materials.