

Researchers hopeful about male partner for 'The Pill'

February 27 2012, By Alan Bavley

Women may say, "It's about time." Guys may have the same reaction. After many overly optimistic predictions, a male version of The Pill may truly be in sight. And a team at the University of Kansas School of Medicine, a nationally recognized center of research into male contraceptives, is working to be among the first to put a new generation of products on the market.

Joseph Tash, a reproductive biologist at KU, has spent a decade tinkering with a [chemical compound](#) called H2-gamendazole that keeps sperm from developing in the testes. Men taking a gamendazole "pill" would essentially be shooting blanks.

The expectation is that men on the KU pill would experience no change in their [libido](#) and, if they stopped taking it, would regain full fertility within a few weeks.

Tash's work is part of a promising array of new [birth control](#) methods for men that are under development in laboratories or already being tested on volunteers. These contraceptives are arriving more than 50 years after the female [birth control pill](#) revolutionized relations between the sexes and gave women greater control over their lives.

Outdated attitudes that birth control was women's work, along with the technical challenges - women release just one egg per month, but men produce 1,000 sperm per second - have slowed development of new male contraceptives. But recent investments in research appear to be

paying off.

Men already are testing contraceptives based on hormones that are analogous to the contraceptive pills women take. Meanwhile, researchers such as Tash are working on compounds that target sperm production or activity directly without affecting men's hormones.

Tash is confident enough about gamendazole that he's getting ready to ask the [Food and Drug Administration](#) what additional studies he'll need to do before he can start trying it on human subjects. "We have enough data now to actually go to the FDA," he said.

He will have to meet a high standard of safety for a drug that healthy men would be taking regularly for a long time; FDA approval, if it goes that far, is perhaps a decade away. So far, though, the compound's safety has checked out in rabbits, mice, rats and monkeys.

Mating tests on rats showed no change in their behavior, Tash said. "And it's 100 percent effective and 100 percent reversible."

No formal mating tests on monkeys yet, but those that took it "still seemed happy," he said.

KU colleagues are working on other promising ways to keep sperm at bay. Leslie Heckert is looking for chemicals that can block the action of a protein essential to an early stage of sperm development. Gustavo Blanco already has a series of compounds that immobilize sperm so they can't swim to an egg; he's seeking about 100 volunteer sperm donors to supply him with the raw material for testing the compounds in the lab.

The prospect of a male pill raises plenty of questions: Will men be willing to take it? Will women trust men to take it? Will it have any effect on the divisive issues of birth control?

Contraception for men has long been limited to a small and dismal set of options - condoms, vasectomy, interruption of intercourse. But that hasn't kept increasing numbers of men from shouldering responsibility for preventing unwanted pregnancies.

Laura Lindberg of the Guttmacher Institute, which does research on reproductive health, traces this change in behavior to the 1980s, when more men started using condoms.

The trend by couples to delay having children had begun, and that created a greater need for contraception. But not all women were able or willing to use contraceptive pills or IUDs. Condoms became a regular part of marriages and long-term relationships.

The '80s also was the era of HIV and other sexually transmitted diseases; condoms became a routine part of safe sex.

"Condoms moved from behind the counter in the drug store to out front, and so did our attitudes," Lindberg said.

In 1982, only 52 percent of sexually experienced women reported ever having had sex with a partner who used a condom. By 2006, it had climbed to 93 percent of women.

"Practically every woman has used a condom now," Lindberg said. "That's a phenomenal social change."

Even so, the proportion of women who said their most recent sex partner used a condom - about one in five - hasn't risen in the past decade.

Elaine Lissner, an advocate who runs the Male Contraception Information Project, thinks more men would use birth control if they had better alternatives.

"To reach more men, you have to have something more attractive than the current choices. Plenty of men already are stepping up to the plate. More would if there was something better," she said. "Men deserve something better."

While men appear ready for a pill of their own, it's not clear how women will react.

Women surveyed in Scotland, South Africa and China expressed almost unanimous confidence in their partners' reliability.

Ajay Nangia, a urologist on Tash's team, has been asking people around Kansas City, about 300 so far, about their attitudes towards a male pill. He hasn't found quite that level of support.

"Do men trust themselves to take it and do women trust the men? Men do trust themselves. Women trust men, but not as much," Nangia said. "It depends on the stage of their relationship."

That suggests a male pill may not change the prospects of men who aren't in stable, long-term relationships.

As Lissner said: "If you don't trust a guy enough to believe he's on the pill, there should be a condom."

Lissner attributes the scant number of male birth control methods available so far to attitudes that started to change only as the more open-minded Baby Boom generation came of age.

For many years, drug manufacturers didn't think men would want their own version of the Pill, Lissner said. Contraception was a women's issue, so the thinking went, and men would be too squeamish anyway to use something they thought might affect their manhood.

But difficulty getting products out of the lab also slowed progress, said Diana Blithe, director of the male contraceptive development program at the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

"It's not that there hasn't been an interest, but the science wasn't always there," she said.

A dozen years ago, drug companies and academic researchers were doing some work on male contraception, Blithe said, but there wasn't a big push to bring innovative methods to market.

Blithe and others at her institute decided to change that by offering research grants specifically for male contraceptives.

"It was a way to stimulate the field, to get researchers thinking of products," Blithe said.

Her institute now provides about \$3 million per year for male contraception projects. An additional \$6 million per year is split evenly between male and female birth control research at the institute's four contraceptive development research centers - Tash's KU program is one of them.

While government research funding has increased, the pharmaceutical industry's commitment to male contraception hasn't kept up.

Blithe points to Schering AG and Organon, large companies that were jointly developing a hormonal male contraceptive. The two dropped their project in 2006 after Schering was acquired by a third company, Bayer.

Industry support will be needed to bring new male birth control methods

to market, Blithe said, and she expects that backing from business will be there when researchers have something promising to show them.

"I think they have a great deal of interest, but not a great deal of investment," she said. "They want to have something that is pretty far along."

When will that be?

John Amory, a male contraceptive researcher at the University of Washington, says there's a joke in his field about such predictions.

"People have been saying it's five years away for 30 years," Amory said. "The history is humbling."

For much of that history, researchers have been trying to develop hormonal contraception for men just as they did for women.

Giving a man the male hormone testosterone alone or in combination with progestin, a synthetic version of the female hormone, progesterone, can trick his body into thinking he has plenty of sperm and testosterone and doesn't need to make any more.

But hormonal contraception doesn't appear to work in all men. And it can have troubling side effects.

Last year, the World Health Organization and CONRAD, a nonprofit contraception research group, shut down an eight-country study of a testosterone-progestin combination after an unexpectedly high number of men experienced depression and other mood changes.

Another problem with testosterone is that an oral version hasn't been available. Injections or other methods are used.

"Most men are interested in a pill," Amory said.

Amory hasn't given up on hormonal contraception for men - he has a clinical study using testosterone and progestin gels. But much of Amory's attention, like Tash's, is directed toward developing a contraceptive that blocks sperm production without resorting to hormones.

Even so, hormonal methods may be the first forms of male contraception to gain FDA approval because they involve drugs that already have been on the market for years.

The FDA probably will set the bar much higher for novel compounds such as those Tash and Amory are working on, and may demand that they be even safer than women's contraceptive pills.

The reason: Men don't face the health hazards of pregnancy.

Women on the pill run a small risk of blood clots, Amory said, but that's considered justified because the risk would be many times higher if the woman became pregnant.

"You can't make the same argument with men," Amory said.

Shifting birth control to [men](#) would eliminate one of the controversies about female contraception, Tash said.

Women's birth control pills stop the ovaries from releasing eggs and block sperm from the cervix. But they also make the uterus unreceptive to the implantation of a fertilized egg, a morally troubling possibility to people who consider this tantamount to abortion.

"The hot issue of when conception occurs won't apply" with a male pill,

Tash said.

But Tash grants that sperm-free contraception won't put every argument to rest.

"It is contraception," he said. "Some individuals are just against contraception. Period."

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