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January 17th, 2026

Dear Regina,

Welcome to the 2026 BioMarketing Insight's monthly newsletter.

Hope everyone had a great holiday and was able to relax and spend quality time with their loved ones, family and friends.

The New Year started off fine, then I was hit by the Bitlocker Recovery Key Disaster for Microsoft Windows 11. For those who've already encountered this problem, you are probably rolling your eyes. For those who have never heard about it, buyer **BEWARE**. This is why my newsletter is a little late this month.

Bitlocker is an an encryption program on your hard drive that Microsoft automatically installed and enabled on your Windows 11 computer that is suppose to prevent

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computer and that you **MUST** create a Bitlocker Recovery Key should that happen. What they also **DON'T** tell you is that Bitlocker is tripped if you mistakenly enter the wrong password too many times, you accidentally hit a combination of keys on your keyboard that will trigger the lock down of your computer. I could be anything. You'll get that dreaded Blue screen asking for your Recovery Key, but it is very confusing as to what they want.

Your Recover Key contains thirty three (33) numbers to gain access to your computer. If you don't have the key which I didn't since I didn't even know about it, the Microsoft (MS) tech support will tell you that you have to reinstall Windows 11 which wipes out all of your files, photos, programs, settings etc. It is basically a factory reset. You have to start from scratch. You do not have the option of reinstalling Windows and keeping your files because Bitlocker thinks your computer is stolen. MS will tell you to go to a local computer tech to get your files off of the hard drive, reinstall windows 11 and transfer your files back to your computer. I found out that you can't get your files off the hard drive because it is encrypted and you still need the key. Similar to it being stolen. The only way you can get your files is if you backed it up in the cloud. If you didn't you are out of luck. But you still have to reinstall all of your programs, apps and input your settings again. Microsoft rating: zero (0).

I nearly had a heart attack when I heard this. I also called HP and they were no help. They said the same thing as the MS tech. Luckily, I went back to the tech shop that helped set up my new computer and transfer my data from old hard drive on to my new computer and they had the recovery key since they set up my computer.

To prevent all this aggravation, you can either create a recovery key or turn off the Device Encryption under Privacy and Security. The computer tech suggested that if I am not traveling with a laptop, such as for a business, then I really don't need BitLocker to be enabled.

This month I will be covering "Why it Took Decades to Develop the First Hormone-Free Male Birth Control Pill". To read this article, just go to the Table of Content and click on the link.

If you missed the newsletter on "Making Sense of it All: DOGE, Government Shut Down, 100% Pharmaceutical Tariff, and the Impact it has on Everyone", click on this [link](#).

The next newsletter will be February 15, 2026.

2025 was a year of uncertainty and chaos. Here is to 2026 being a year of calm and positive certainty. But if you need a little inspiration or something to make us laugh to

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song "What the World Needs Now," and ending with Celine Dion and Josh Groban with "The Prayer".

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.



Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
[BioMarketing Insight](#)



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Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact [me](#) for an appointment. For successful commercial adoption of your product or looking to grow your business, contact [me](#) for an appointment.

For more information on our services, click on the links below:

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BioProcess International

September 15 -18, 2025
Hynes Convention Center,
Boston, USA

Creating a Winning Target Product Profile: A Roadmap for Successful Biopharmaceutical Development

Use Code SPEAKER10 and Save 10%

Part of:
Biotech Week Boston

Regina Au,
CEO, New Product Planning/Strategic Planning,
BioMarketing Insight

Recap: September 15-18, 2025 BioProcess International, Boston

I am pleased to announce that I spoke at the BioProcess International Conference on September 17th, 2025. The title of my presentation is "Creating a Winning Target Product Profile: A Roadmap for Successful Biopharmaceutical Development". For more information on my presentation, click [here](#). For more information on the agenda and other speakers, click [here](#).

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HYBRID EVENT: You can participate in person at Orlando, Florida, USA or Virtually from your home or work.

IVC 2025 Home Scientific Committee Speakers Program Information About Contact Submit Abstract Register

5th Edition of International Vaccines Congress

October 23-25, 2025 | Orlando, Florida, USA

🔔 Tentative Program

🔔 First Round of Abstract Submissions Closes on May 29, 2025

🔔 Early Bird Registrations Closes on May 30, 2025

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I am pleased to announce that I was be a Key Note Speaker and a Scientific Committee Member at the IVC 2025 Conference in Orlando, FL, October 23 - 25, 2025. The title of my presentation is "[The importance of post-marketing surveillance and real-world data: For a product to be successful](#)". Information on Scientific Committee members, click [here](#). For more information on the conference, click [here](#).

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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.

Even with the current uncertainty of our country, we will get through it. Keep voicing your opinion on what is right, what is wrong and the needs of the people. This is the only way things will change.

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Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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Why it Took Decades to Develop the First Hormone-Free Male Birth Control Pill

Birth control contraceptives are not new, but the responsibility have fallen on the women to use contraceptive despite the horrible and risky side effects associated with them. Most women will take the pill or use a physical device called an IUD, implants, patches and injections whereas male contraception usage consists of condoms or vasectomies.

There are a number of reasons for this, some understandable, others unfair due to old-fashioned societal culture or mindset.

1) **Biology**: One of the obstacles to developing male contraception is simply a matter of

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from getting another person pregnant.

“What you’re trying to achieve is very different,” says. “In women, you’re preventing one cell being released once a month, whereas in men, you’ve got to stop millions of sperm every minute.” In a female reproductive system, one egg is released per cycle – on average every 28 days – in a process governed by fluctuating hormones.

Dr [Channa Jayasena](#), reproductive endocrinologist at Imperial College London, says: “It’s relatively easy to disrupt the menstrual cycle with hormone exposure, because you just wreck the balance that’s involved in growing eggs and releasing them.”

So, most female contraceptives – such as pills, implants, patches, injections and some coils – introduce extra female sex hormones, namely synthetic versions of progesterone (and sometimes oestrogen) to prevent any eggs from being released at ovulation.

Jayasena adds that “Men are fundamentally different, because they make their gametes all the time, and they make millions of them.”

“It takes three months to make sperm, so there’s this constant conveyor belt, and any contraceptive has to inhibit the testes for a very long time.”

That means any male contraceptive would need to be used for three months before reliably preventing pregnancy, otherwise there might still be sperm in the system.

Female hormonal contraception is usually effective after seven days – or immediately – depending on when in the cycle someone starts to use it compared to three months with males.

Jayasena explains: “It is much easier to suppress female hormones because they’re at much lower quantities – orders of magnitude lower than testosterone.”

In order for male hormonal contraception to work, it must pump far more males hormones, testosterone into the body compared to female hormonal contraception. To pump that much testosterone into the body comes with dangerous health risks. So, to avoid dangerous side effects, male hormonal contraception are combines with a female sex hormone, called progesterone which had side effects. Males do have progesterone in their bodies naturally, but in very small quantities.

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Source: Liudmila Chernetska via Getty

2) **There's no money in male contraceptives:**

Jayasena believes that the pharmaceutical companies who would usually develop this kind of medical technology “don’t think it’s going to be a lucrative market”.

[Condoms](#) have been around for at least 300 years, relatively cheap, widely available, offer bonus protection against sexually transmitted infections, and are 98 percent effective against pregnancy if used properly.

[Kate Muir](#), women’s health campaigner says the answer is simple: “New research costs billions. Nobody’s going to spend it on men when women are already doing the work.”

Anderson agrees with Muir. He says: “There’s been a perception, going back many decades, that female contraception has got the market sewn up and there’s nothing more to be done.”

“If you’re developing a new contraceptive, it’s got to be very cheap, because female contraception is generally very cheap,” Anderson says. “It’s got to be 100 per cent perfectly effective, and it’s got to have zero side effects, because that’s what people want for contraception.”

He also believes, is that many pharmaceutical companies “are still run by conservative middle-aged men whose bottom line is their financial spreadsheets.”

Funding has been a continual challenge for the field. The National Institutes of Health ([NIH](#)) currently provides nearly all the funding for male contraception research in the U.S. —as well as some international studies. Researchers agree that for a new contraceptive to come to market, support from pharmaceutical companies is a practical necessity, but interest in the industry has been waning in recent years.

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because they don't have a risk. They are not going to get pregnant.

“So, if there's a little bit of a side effect – that counts against their perfect health, whereas for us, it counts against a risk of pregnancy.”

In a [2016 male contraceptive trial](#) using testosterone and progesterone, it was stopped early due to numerous side effects and 20/250 participants dropped out. The most commonly reported adverse events were acne, changes to libido and low mood – all of which are already accepted side effects of female hormonal contraception. But the efficacy was 96%.

Men have the same level of hormones all the time, bar some daily variations,” says Anderson, explaining that testosterone levels are highest in the morning.

In contrast, says Jayasena: “Women have a fundamentally cyclical relationship with their hormone environment and, particularly in the premenstrual phase, they will have different symptoms.”

Basically, women are expected to cope with changing hormones and side effects associated with that and female contraceptives, whereas with men, Jayasena says this is “an alien concept” and the 2016 trial was discontinued because the author decided it probably wasn't worth finishing it even though it was nearly finished.

Andersons believes more couples are considering contraceptives as a joint endeavour, with risks and benefits shared between a couple.

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First Hormone-Free Male Birth Control Pill Shown Safe in Early Human Trials

[YCT-529](#), a retinoic acid receptor- α antagonist is a non-hormonal contraceptive just finished its first safety trial in humans, the first step towards getting FDA approval for the first male contraceptive pill.

Researchers have been chipping away at this problem for the past 40 years. This is an entirely new kind of contraceptive mechanism tested in humans. The daily pill, YCT-529, blocks a vitamin A metabolite from binding to its receptor in the testes; this action prevents the chain of gene-expression changes that are required to start the sperm-making process. Animal research from the University of Minnesota College of Pharmacy, published in [Communications Medicine](#), laid the groundwork for the first hormone-free male birth control pill to enter clinical trials.

The [clinical trial](#) involving 16 healthy men were divided into two arms; 1) the drug with escalating dosages and 2) the placebo. Across dosages, “we saw good and quick bioavailability,” indicating the drug didn’t rapidly break down in the body, said Nadja Mannowetz, co-founder and chief science officer of YourChoice Therapeutics.

The research team didn’t note any adverse side effects related to the drug, an advantage with a nonhormonal contraceptive and in theory, there’s a smaller chance of certain side effects such as changes to sexual function, libido or mood, Mannowetz says.

While the results are exciting and important, [Stephanie Page](#), an endocrinologist at the University of Washington School of Medicine, who wasn’t involved in the study points out

The trial did not assess the pill's efficacy in reducing sperm counts, but the drug's developer, YourChoice Therapeutics, is currently running trials to collect this data.

[Page](#) who has worked on other male hormonal contraceptives for more than 20 years said. "We really need more reversible contraceptive methods for men."

Other Male Contraceptives in Development

Several other reversible male birth-control methods are now in the clinical trial pipeline as well.

1) The furthest along is [NES/T, a combination of testosterone and the progestin medication Nestorone](#). Applied daily as a gel to the shoulders and upper arms, it is absorbed into the bloodstream through the skin. Like the YCT-529 pill, the gel targets sperm production, but it does so by increasing the amount of circulating testosterone and progestin—hormones that tell the brain to halt the production process. Researchers have just completed a larger, longer phase 2 clinical trial of NES/T to show effectiveness and hope to start a phase 3 trial soon, says Page, who has been involved in the gel's clinical research.

Users of a male contraceptive that targeted sperm production, such as NES/T or YCT-529, would need to take it daily for about three months before it took effect, because it takes that long for the body to produce mature sperm cells. Sperm production would resume about three months after a user stopped taking the medication.

2) A [couple of other](#) candidates for hormonally acting daily male contraceptive pills are in early development. A hydrogel implant called [ADAM](#) is also being tested in early clinical trials. ADAM acts as a reversible vasectomy, physically blocking off the vas deferens to prevent sperm release until the implant is removed.

3) Dimethandrolone undecanoate ([DMAU](#)) is a once-daily pill that suppresses two types of male hormones – follicle-stimulating hormone (FSH) and luteinizing hormone (LH) – to simultaneously decrease production of testosterone and sperm without causing symptoms of low-testosterone (low-T).

A [published study](#) suggests DMAU, the current oral contraception evaluated, has the potential to do just that. Eighty-two men ages 18 to 50 were randomly given either a placebo or one of three doses of the pill for 28 days. Those who took the highest dosage (400 mg) had lower levels of testosterone, FSH, and LH. However, the study did not measure sperm count.

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- Acne, Headaches Mild erectile dysfunction, Reduced sex drive, Tiredness and Weight gain of 5 lbs. or less

The next steps in studying DMAU will be to determine whether it suppresses sperm production. Initial data indicates that it's possible. However, the body needs up to 90 days to produce sperm, and longer trials are necessary to confirm whether sperm production can be stopped completely.

Longer studies are needed to determine the long-term effects on the body. For example, it is not known yet whether DMAU can cause depression issues or increase the risk of blood clots similar to the female birth control pill, or whether it might damage the liver, kidneys, or other organs that help break down the drug.



Male Contraception Checklist

- Male contraception is possible and does not reduce the strength of the man or his sexual power and prowess.
- There are currently only two methods of male contraception: condoms and vasectomy. Condoms have a relatively low rate of effectiveness (~85%) and vasectomy is intended to be permanent.
- Male contraception will help support women who are exposed to health risks and painful side effects with some of their Family Planning methods.
- Male contraception can help significantly reduce medical expenses related to unintended pregnancies.
- Sexually active youths in university should embrace the use of male contraception as a method to reduce unplanned pregnancy and abortions.
- Women should be proactive in encouraging and educating men on the need to use existing methods of male contraception, while demanding even more and better methods.
- Preventing an unintended pregnancy is a shared responsibility between partners, and benefits all people.
- Sexual Education needs to include male involvement in family planning, including the use of contraceptives.



Please visit www.malecontraceptive.org for more information!

Why it is Important to Have Both Female and Male Birth Control Pills

[About half of pregnancies in the U.S. are unplanned](#) and half of these ends in abortion. An effective male contraceptive might have salutary implications for population growth worldwide, but for [William Bremner](#), who leads the Center for Research in Reproduction and Contraception at the University of Washington (U.W.) in Seattle, the goal is providing options to individual couples. "If people had effective methods and real choices, there would be fewer unwanted children and markedly fewer abortions," he says.

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Pharmacy where the drug molecule was developed. “It will allow a more equitable sharing of responsibility for family planning and provide reproductive autonomy for men.”

There are [many reasons](#) couples consider male birth control. The pill isn’t foolproof, your partner may not be able to take the pill because of side effects or the couple may not use any forms of birth control.

Women also tend to bear most of the cost of birth control, and female methods tend to be costlier than those for men. If you want to play a more equal role, talk with your partner about the best way to do so. Using male birth control can empower couples to have more control over their health and family planning options.

Studies show growing interest. A paper published in 2023 found that , [75 percent](#) of more than 2,000 men surveyed in the U.S. and Canada were willing to try novel contraceptives. A 2019 report found that among U.S. men ages 18 to 49 who had sex with women, did not have a vasectomy or beliefs that prevented the use of contraception, and did not want their partner to become pregnant, nearly [50 percent](#) were “very interested.” These stats line up with Page’s experience in the field: “Men are very eager to have more reproductive agency and to participate in contraception,” she says, and all these contraceptives in the pipeline could elevate individuals’ and couples’ decision-making about sex and reproduction.

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Closing Thoughts

It is refreshing to know that couples or the newer generation couples, both males and females are taking responsibility and sharing the risk in using contraceptives in preventing

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The woman bores majority of the responsibilities since she is one who gets pregnant and therefore, society expects the women to prevent getting pregnant. Since a woman already goes through hormonal changes during her menstrual cycle and experiences side effects, men feel that the side effects from birth control that women experiences are acceptable and normal. Yet, when men go through the same side effects from male hormone birth control in clinical trials, it is unacceptable. This is a perfect example of double standards against women.

If a woman gets pregnant, she goes through nine months of hormonal changes, mood swings, nausea, bloating, back pain, sensitivity in her breast, can't tie her shoes, weird food cravings and the list go on. What do men experience if they are not sharing the responsibility? **Nothing!** And the men who are not willing to share the responsibility experience after the child is born? **Nothing**, unless there is a court order for child support. The woman is responsible for the cost of raising a child by herself. HOW IS THIS FAIR?

To prevent unwanted pregnancies, both the woman and the man must use contraceptives, and the pill is probably the one that will be most used. Male birth control - 96% effective, women birth control - 99% effective **if** both are used as directed or effectively. And we know how reliable that is. So having another birth control will make it hopefully 99.99% effective. I also think there should be the information about male contraceptives in if there is still classes in sex education and education when a boy sees a pediatrician. The same type of programs that are offered for females should also be offered to males as well. This will help with adoption or acceptance of male contraceptives.

I also think that if a man experiences the same side effects as a woman from a birth control pill, he would be more understanding of what a woman goes through if he doesn't already know or can empathize with women. This will make the pregnancy go more smoothly and more pleasant.

This world would be so much better if there were no unwanted pregnancies whether the couple decides to raise the child or not.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at

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