First Condom Authorized Specifically for Anal Intercourse

In a first, the FDA has authorized condoms specifically indicated to help reduce sexually transmitted infections (STIs) during anal intercourse. The devices, marketed as the One Male Condom, also are authorized for reducing the risks of pregnancy and STI transmission during vaginal intercourse.

In a trial involving 252 men who have sex with men and 252 men who have sex with women, clinical failure was lower for anal sex at 0.7% than for vaginal sex at 1.9%. The study examined a total of 2351 anal and 2533 vaginal sex acts. Failure was defined as condom slippage, breakage, or both.

However, due to study design, nearly all anal sex acts—98.3%—used condom-compatible lubricant while only 41.6% of vaginal sex acts used lubricant. Lubricant use reduced failure rates for both anal and vaginal sex, with failure rates similar for the 2 groups when using lubricant. Because condom failure rates were significantly lower with lubrication, condom promotion programs should consider distributing lubricant as well, the study authors suggested.

The FDA authorization applies to 3 different versions of the condoms—standard, thin, and custom-fit. There was no difference in failure rates for anal sex among the 3 condom types in the trial.

Unprotected anal intercourse has the greatest sexual exposure risk of transmitting HIV, according to the FDA. "In the largest trial of effectiveness of condoms for anal sex to date, we found remarkably low levels of failure," the study authors wrote. "Clinicians may recommend condoms as a highly efficacious HIV and [sexually transmitted disease] prevention tool for anal sex."

FDA Expands Empagliflozin Heart Failure Indication

Empagliflozin, marketed as Jardiance, is a sodium–glucose cotransporter 2 inhibitor that was initially approved in 2014 for glucose control among patients with type 2 diabetes. It was also previously approved to reduce death and hospitalization for patients with type 2 diabetes and cardiovascular disease, as well as for patients with heart failure and low ejection fraction with or without diabetes.

"Today’s approval will provide a treatment option for a wider range of patients with heart failure," Norman Stockbridge, MD, PhD, of the FDA’s Center for Drug Evaluation and Research, said in a statement.

The expanded indication is based on a phase 3 trial in which 5988 patients with class II through IV heart failure and preserved ejection fraction were randomly assigned to receive 10 mg empagliflozin once daily or placebo in addition to usual therapy. The primary outcome was a composite of cardiovascular death or heart failure hospitalization.

Over a median of 26.2 months, 13.8% of 2997 patients in the empagliflozin group died or were hospitalized for cardiovascular causes compared with 17.1% of 2991 patients in the placebo group. The effect was mainly due to lower hospitalization risk in the empagliflozin group and was consistent across patients with and without type 2 diabetes.

Uncomplicated genital and urinary tract infections and hypotension were reported more often with empagliflozin. The FDA cautioned that patients receiving dialysis should not use the drug.

New Cancer Clinical Trial Guidance

The FDA has issued 3 final clinical trial guidance documents to promote further advances in cancer prevention, detection, research, and patient care. The documents’ goals parallel President Joe Biden’s recent promise to build on his 2016 Cancer Moonshot, according to an FDA statement.

The first guidance encourages increased participation of patients aged 65 years or older in cancer clinical trials, including in early phases to better inform later-phase studies. It also offers recommendations for trial design, recruitment strategies, information collection, and results reporting by age cohort to support enrollment of this historically underrepresented population.

The second document, on expansion cohorts, could help increase the efficiency and speed of cancer drug development. It provides advice on designing and conducting trials that enable concurrent accrual of patients into multiple cohorts to assess the safety, pharmacokinetics, and antitumor activity of first-in-human cancer drugs. This would allow a drug’s many different aspects to be simultaneously evaluated in a single clinical trial.

The final document offers guidance on developing and reporting results from master protocol trial designs, which enable more than 1 investigational drug or biologic, disease type, or patient population to be evaluated under a unified clinical trial structure.

Biden aims to reduce the cancer death rate by at least 50% over the next 25 years. Although not compulsory, the guidance documents may help drug developers work better with the FDA while protecting patient safety and data accuracy.

~ Howard D. Larkin

Note: Source references are available through embedded hyperlinks in the article text online.