U.S. approves first-ever DNA alternative to Pap smear

Matthew Perrone - AP Health Writer - Associated Press

Federal health regulators have cleared a genetic test from Roche as the first ever U.S.-approved alternative to the Pap smear, the decades-old mainstay of cervical cancer screening.

The Food and Drug Administration approved Swiss-based Roche's cobas HPV test to detect the human Papillomavirus, or HPV, in women 25 and up. HPV causes nearly all cases of cervical cancer.

Doctors already use such DNA-based tools as a follow-up to confirm Pap test results. But Thursday's decision means Roche can now market its test as a stand-alone option for cervical cancer screening, ahead of the Pap test.

Roche supported its bid for expanded marketing with study results suggesting genetic testing is more accurate and objective at identifying cancerous growths than Pap smear—which requires doctors to examine cervical cells under a microscope for signs of cancer.

The FDA approval comes despite pushback from a number of women's health groups, who warned regulators that approving the DNA test as an alternative to Pap testing could lead to confusion, higher costs and overtreatment. More than a dozen patient groups raised those concerns in a letter to the FDA last week. Specifically, they said HPV-only testing could lead to overtreatment of younger women who carry the virus but have little risk of developing actual cancer. Most sexually active young people contract HPV, though their bodies usually eliminate the virus within a few months. Only years-long infections develop into cancer.

FDA officials said in a statement Thursday that they approved the test because "Roche Diagnostics conducted a well-designed study that provided the FDA with a reasonable assurance of the safety and effectiveness." The trial included over 47,000 women who underwent cervical screening using either Pap or HPV screening. The test results were then checked for accuracy against final biopsy results that confirmed whether they actually had cancer.

For decades the Pap test was the only screening option for cervical cancer—and it's had a remarkably successful track record. The number of cervical cancer cases reported in the U.S. has decreased more than 50% in the past 30 years, primarily due to increased Pap screening. Still, an estimated 12,000 cases of cervical cancer are expected to be diagnosed this year, a fact that has spurred development of HPV tests like those from Roche, Qiagen and other test makers. HPV test costs generally cost between $80 and $100, about twice as much as a $40 Pap.

Medical guidelines have been evolving rapidly to try and incorporate both techniques. Under the latest guidelines from the American Cancer Society, a Pap test is recommended every three years for women 21 to 29 years old. Women 30 and older should have both a Pap test and an HPV test every five years, or a Pap test alone every three years. HPV screening is not recommended for women in their 20s because it increases the odds of more invasive testing that can leave the cervix less able to handle pregnancy later in life.

But the FDA approval allows Roche to market its test for women as young as 25. Women who test positive for the most high-risk strains of HPV will be referred directly to colposcopy, an invasive test in which doctors view the cervix with a magnifying device and often collect a tissue sample for testing.

Groups including the Cancer Prevention and Treatment Fund, American Medical Women's Association and Our Bodies Ourselves questioned why the FDA would approve labeling that goes against medical society recommendations—which only recommend HPV screening for women 30 and older.

In its statement approving the test, the FDA staff suggested its decision would not change how doctors use HPV screening.

"It does not change current medical practice guidelines for cervical cancer screening. These guidelines are developed, reviewed and modified by groups other than the FDA," said Dr. Alberto Gutierrez, who oversees the FDA's testing office.

But the women's groups rejected that reasoning.

"They imply that the FDA approval decision isn't that important in deciding how this test will be used," said Diana Zuckerman, president of the Cancer Prevention and Treatment Fund. "By claiming to pass the buck to the experts in the field, FDA is not taking responsibility for the agency's influential decision to approve the test as a replacement of the Pap smear for women over 25."

Roche said in a statement that the FDA approval "is recognition for the value the cobas HPV test provides to physicians and women to make more informed decisions."