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DNA alternative to Pap smear sparks medical debate (Update)

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A high-tech screening tool for cervical cancer is facing pushback from more than a dozen American patient groups, who warn that the genetic test could displace a simpler, cheaper and more established mainstay of women's health: the Pap smear.

The new test from Swiss drug maker Roche uses DNA to detect the human papillomavirus, or HPV, which causes nearly all cases of cervical cancer. While such technology has been available for years, Roche now wants the Food and Drug Administration to approve its test as a first-choice option for cervical cancer screening, bypassing the decades-old Pap test.

But a number of women's groups—including the American Medical Women's Association and Our Bodies Ourselves—warn that moving to a DNA-based testing model would be a "radical shift" in medical practice that could lead to confusion, higher costs and overtreatment.

"It replaces a safe and effective well-established screening tool and regimen that has prevented cervical cancer successfully in the U.S. with a new tool and regimen not proven to work in a large U.S. population," state the groups in a letter to FDA Commissioner Dr. Margaret Hamburg. The letter, dated Monday, is signed by 17 patient advocacy groups, including Consumers Union, the Cancer Prevention and Treatment Fund and the National Alliance for Hispanic Health.

Chief among the advocates' concerns is that 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 will contract HPV, though their bodies usually eliminate the virus within a few months. Only years-long infections develop into cancer.

"Unfortunately the HPV test by itself isn't very useful because so many young women have HPV that will disappear without any treatment," said Diana Zuckerman of the Cancer Prevention and Treatment Fund. "Having an HPV test without also getting a Pap smear to check for problems is going to scare a lot of women who are not developing cervical cancer."

An FDA spokeswoman said the agency could not comment on the letter since it deals with a product under review.

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 percent 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 genetic tests like the one from Roche and other test makers.

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. Women who have had an HPV vaccine should still follow screening guidelines.

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 Roche is seeking FDA approval to market its test to women age 25 and up.

That approach was endorsed unanimously last month by a panel of FDA advisers who voted 13-0 that Roche's cobas HPV test appears safe and effective as a first-choice screening tool. The FDA is weighing that recommendation as it considers approval the company's application.

Despite the overwhelming endorsement, patient advocates say FDA approval would fly in the face of current medical guidelines, none of which recommend testing with HPV alone for younger women. They point out that the U.S. Preventive Services Task Force, which sets federal medical guidelines, gave HPV testing a "D" rating in women under age 30, warning that testing could lead to "unnecessary treatment and the potential for adverse pregnancy outcomes."

Even physicians who support HPV testing as an important option warn that introducing a DNA-only testing regimen may lead to confusion that disrupts care. The American College of Obstetricians and Gynecologists says many physicians are already confused by the two existing testing options: Pap alone or Pap with HPV testing.

"Introducing a third screening alternative will likely further increase confusion, and the risk to women of getting either over or under screened," the group said in comments at the FDA meeting last month. The group, which represents 57,000 U.S. obstetricians and gynecologists, did not sign the letter sent to FDA this week.

Finally there is the cost. An HPV test costs between $80 and $100, at least twice as much as a $40 Pap. And under Roche's proposal, women who test positive for HPV would be referred for colposcopy, a more invasive testing procedure that can cost up to $500.

All these factors have consumer advocates urging the FDA to break from its advisers and deny first-choice status to the Roche test.

"Sometimes the FDA overrules the advisory committee and it's OK," said Dr. Susan Wood, a former FDA official who now directors the Jacobs Institute of Women's Health.