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INSIDE

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With Reclassification and New Name, Doors May Open for Internal Condom

Once known as the female condom, the device now is recognized for vaginal and anal use

The Food and Drug Administration (FDA) has reclassified the female condom from a Class III device to a Class II device, putting it in the same category as the male condom. With the reclassification comes a new name — from "single-use female condom" to "single-use internal condom" — in recognition of its use in both vaginal and anal sex. What do these changes mean for the method?

Reproductive health clinicians in the United States are familiar with the FC2 internal condom, marketed by The Female Health Company, a division of Veru Healthcare of Miami. The FC2 condom is made up of a nitrile (non-latex) sheath and outer ring, with an inner ring of polyurethane. The product does not include spermicidal additives, but it contains a silicone-based lubricant on the interior and exterior.

"The renaming of the class of devices to which the FC2 belongs is important not only for the new implied indication (anal application), but also because it also helps reinforce the trend to be less dichotomous in terms of gender identity," states **Anita Nelson**, MD, professor and chair of the obstetrics and gynecology department at Western University of Health Sciences in Pomona, CA. "Instead of distinguishing between 'male' and 'female' condoms, we can discuss 'external' and 'internal' condoms."

Members of the National Female Condom Coalition (NFCC) pushed for the device's reclassification. NFCC is a partnership of advocates, researchers, health departments, and community-based and national organizations based in the United States. By moving the device to a Class II ranking, advocates believe it will open the door for more internal

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condom options. The transition from a Class III to a Class II designation lessens the burden on manufacturers when seeking FDA approval for internal condom devices.

"We are thrilled to learn about these changes and so grateful for the tireless efforts of sexual health advocates across the globe who worked for years to demand greater access to this prevention method, which truly empowers people to take control of their health on their own terms," said **Sara Semelka** of the AIDS Foundation of Chicago, in a press statement. The AIDS Foundation of Chicago serves as the NFCC Secretariat.

Roxanne Lewis is the program coordinator for Healthy Alternatives for Reducing the Risk for HIV Program at JWCH Institute in Los Angeles. She has provided female condom training to more than 200 health providers.

"I fought for this because I believe there is power in choice, and I was turned on every time someone said, 'I didn't know about [the female condom],'" said Lewis in a press statement. "The FDA made the right decision, and I hope this turns the tide for greater choice in prevention and safer-sex options."

> "THE RENAMING OF THE CLASS OF DEVICES TO WHICH THE FC2 BELONGS IS IMPORTANT NOT ONLY FOR THE NEW IMPLIED INDICATION ... BUT ALSO BECAUSE IT ALSO HELPS REINFORCE THE TREND TO BE LESS DICHOTOMOUS IN TERMS OF GENDER IDENTITY."

Why Is Reclassification Important?

The FDA categorizes medical devices into three classes based on their risks and the regulatory controls needed to assure safety and effectiveness. A Class III device requires the greatest amount of clinical evidence and control, which in turn pushes up the costs and efforts to reach premarket approval. Pacemakers and breast implants, for example, are considered Class III devices.

The male condom was ranked as a Class II device in 1981 because of the FDA's determination that sufficient evidence existed for safety and effectiveness. However, when the FC2's predecessor, the FC1 female condom, was evaluated in 1991, the device was not found to be "substantially equivalent" to the male condom, and subsequently received a Class III device designation.

Since the FC1's initial approval and the FC2's approval in 2009, additional female condom products have emerged, achieving regulatory approvals and prequalification by the World Health Organization, as well as marketing approval in other countries. Advocates say the Class III designation has deterred some female condom manufacturers from pursuing FDA approval for their products in the United States. With the reclassification, potential internal condom manufacturers no longer have to submit an application for premarket approval. Instead, companies can provide a 510(k) premarket submission to demonstrate

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The Food and Drug Administration has reclassified the female condom from a Class III device to a Class II device, putting it in the same category as the male condom.

- With the reclassification comes a new name — from "single-use female condom" to "single-use internal condom" — in recognition of its use in both vaginal and anal sex.
- The only internal condom currently available in the United States, the FC2 internal condom, is sold by prescription only. For those without insurance, it also is available for purchase online through the manufacturer, and may be available for patients at health departments or clinics.

that the device is substantially equivalent to another device that is legally marketed in the United States.

Design firm IXu of Petoskey, MI, plans to seek FDA approval in early 2019 for its VA "worn-of-women" line of internal condoms. In September 2018, the firm announced a new contract with manufacturer HLL Lifecare Ltd., a government-owned device company in India, to kick off its European sales.

Gender-neutral Name Removes Barriers

Advocates say the renaming of the female condom sets the stage for greater inclusivity, especially for the LGBTQ community. Observational studies in the United States indicate that some men who have sex with men use the female condom for anal intercourse.[1-3]

In its September 2018 regulatory action, the FDA made the following statement: "The device is assigned the generic name single-use internal condom, and it is identified as an OTC [over-the-counter] sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes."[4]

Data indicate that anal intercourse is a common practice in the United States. Among men ages 25 to 44, 3.9% report having had anal intercourse with another man, and 40% say they have had anal intercourse with a woman. Among women ages 25 to 44, 35% report having had heterosexual anal intercourse.[5] Such practice is a concern for public health officials: Unprotected anal intercourse is the sexual activity associated with the highest risk of HIV infection.[6]

Over-the-counter Access Underlined

The FC2 internal condom currently is sold by prescription only in the United States. For those without insurance, it also is available for purchase online through the manufacturer, and may be available for patients at health departments or clinics. The price for all public sector and 501(c)(3) entities, based on a box of 1,000, is $1.10 per device, starting Jan. 1, 2019. The Female Health Company is the only organization selling the FC2 condom directly to the U.S. public sector.

According to the FDA ruling, the single-use internal condom is designated as an over-the-counter device. Reproductive health advocates say the classification should open the door for greater access, bringing internal condoms to the drugstore shelves. ■

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FDA Move Widens Approved Use of Human Papillomavirus Vaccine

The Food and Drug Administration (FDA) has approved the use of the nine-valent human papillomavirus (HPV) vaccine in women and men ages 27 through 45. What are the next steps in implementing immunization for this expanded age range?

The October 2018 approval represents an "important opportunity" to aid in the prevention of HPV-related diseases and cancers in a broader age range, says **Peter Marks**, MD, PhD, director of the agency's Center for Biologics Evaluation and Research.

"The Centers for Disease Control and Prevention has stated that HPV vaccination prior to becoming infected with the HPV types covered by the vaccine has the potential to prevent more than 90% of these cancers, or 31,200 cases every year, from ever developing," said Marks in a press statement.

The nine-valent vaccine was approved for use in 2014. In October 2016, updated HPV immunization recommendations were issued regarding dosing schedules. The Centers for Disease Control and Prevention (CDC) currently recommends two doses of HPV vaccine for people starting the immunization series before their 15th birthday. The agency recommends the administration of three doses of HPV vaccine for people starting the series on or after their 15th birthday, as well as for people with certain immunocompromising conditions.

The CDC recommends routine immunization for children 11 or 12 years of age, but the series can be initiated at 9 years of age. Immunization also is recommended through age 26 for females and through age 21 for males. Males ages 22-26 may be immunized.[1]

In a practice advisory to its members, the American College of Obstetricians and Gynecologists states that it is working with the CDC to determine appropriate changes in clinical guidance and recommendations.[2] Until changes are approved, clinicians should continue to follow current guidance. Providers are encouraged to welcome conversations with women older than age 26 who are interested in receiving the HPV vaccine, the advisory states. Decisions to be immunized should be made using shared decision-making and clinical judgment based on individual patient circumstances, preferences, and concerns. Research indicates the vaccine is safe and effective in preventing new HPV infections in women in the age 27-45 category.[3]

More Data to Be Presented in February

Should the upper age for HPV catch-up vaccination be expanded beyond the current recommendation? A work group of the Advisory Committee on Immunization Practices (ACIP) still is reviewing results from health economic analyses, as well as other data related to this policy question. The committee is scheduled to review further information and economic analyses at its February 2019 meeting, with a potential vote at that time.

Although the FDA approval of an expanded age range is important, many insurance companies look to ACIP recommendations when determining whether to extend coverage. Coverage may not be available until such recommendations are issued.

According to information presented at the October 2018 ACIP meeting, HPV vaccines have been licensed through age 45 or older in other countries. However, no country has

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The Food and Drug Administration has approved the use of the nine-valent human papillomavirus (HPV) vaccine in women and men ages 27-45. The Advisory Committee on Immunization Practices (ACIP) is scheduled to review further information at its February 2019 meeting, with a potential vote at that time. Insurance reimbursement often is based on ACIP guidance.

- Current recommendations call for administering two doses of HPV vaccine for people who start the immunization series before their 15th birthday. For people who start the vaccine series on or after their 15th birthday, three doses of HPV vaccine are recommended. The same three-dose recommendation applies to people with certain immunocompromising conditions.
- Routine immunization is recommended for children at age 11 or 12, but the series can be started at 9 years of age. Immunization also is recommended through age 26 for females and through age 21 for males. Males ages 22-26 may be immunized.

a public health HPV vaccination program targeting mid-adults, which is the term public health officials now are using for the 26-45 age category.

The FDA summary basis for its regulatory action centered around research looking at use of the vaccine in both women and men.[3-7] These studies include additional follow-up of patients enrolled in studies of the four-valent vaccine and observational studies lasting up to 10 years. Understanding the potential benefit of vaccination in adults is complex; HPV is common, with infection occurring soon after initiation of sexual activity, said **Lauri Markowitz**, MD, HPV team leader in the CDC's Division of Viral Diseases at the October 2018 ACIP meeting. There are challenges in studies of HPV incidence, since HPV detection cannot distinguish between new or persistent infections and redetection of infection, she noted.

New infections do occur in adults, and sex with a new partner is a risk factor, said Markowitz. The percentage of adults with a new partner in the past year decreases in older age groups. Contributing to the complexity of the issue is that not all infected individuals develop antibodies, she stated.

The work group will continue to conduct a further review of the health economic analyses, summarize values and acceptability in the expanded age group, review data for special populations, discuss policy options, and complete evidence reviews in preparation for a potential vote at the February 2019 meeting, said Markowitz. ■

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Researchers Release Initial Results on Developmental Vaginal Ring

Despite impressive strides in prevention and treatment, AIDS-related illnesses remain the leading cause of death worldwide among women of reproductive age (ages 15-49).[1]

In an effort to provide both HIV/AIDS and unintended pregnancy protection, researchers have developed a vaginal ring containing the antiretroviral drug dapivirine and the contraceptive hormone levonorgestrel. Scientists have just released results of an initial clinical trial, noting no safety issues.[2]

(Contraceptive Technology Update *reported on the start of this research in the August 2017 article, "Dual-purpose Vaginal Ring Moves to Clinical Trial," at https://bit.ly/2B4V1rP.*) What are the next steps for research?

In the initial trial, conducted at Magee-Womens Hospital in Pittsburgh and the University of Alabama at Birmingham, women used the device for 14 days to allow researchers to assess its safety, as well as to measure uptake of its two drugs. The ring under study contains 200 mg of dapivirine and 320 mg of levonorgestrel. Based on the positive results, researchers are launching a second Phase I trial, in which participants will use the device for 90 days.

With the start of a second study underway, scientists are closer to potentially offering an easy-to-use product with effective and long-acting protection against HIV and unintended pregnancy, said **Sharon Achilles**, MD, PhD, assistant professor of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of

EXECUTIVE SUMMARY

In an effort to provide both HIV/AIDS and unintended pregnancy protection, researchers have developed a vaginal ring containing the antiretroviral drug dapivirine and the contraceptive hormone levonorgestrel. Scientists have just released results of an initial clinical trial, noting no safety issues.

- Despite impressive strides in prevention and treatment, AIDS-related illnesses remain the leading cause of death worldwide among women of reproductive age (ages 15-49).
- U.S. and global regulatory approval is being sought for a 25 mg dapivirine-only vaginal ring. If it is approved, the monthly ring would be the first biomedical HIV prevention method developed specifically for women.

Medicine and director of the Magee-Womens Research Institute Center for Family Planning Research, in a press statement. Achilles serves as protocol chair for the study, a joint effort of the International Partnership for Microbicides (IPM), a nonprofit research group based in Silver Spring, MD, and the U.S. National Institutes of Health-funded Microbicide Trials Network (MTN), based at Magee-Womens Research Institute and the University of Pittsburgh.

"We believe in the promise of multipurpose prevention and [the] results of the first study of the three-month dapivirine-contraceptive ring are welcome progress toward meeting women's overlapping sexual and reproductive health needs," states **Zeda Rosenberg**, ScD, IPM founder and chief executive officer.

Progress in the Pipeline

The IPM is seeking U.S. and global regulatory approval of a 25-mg dapivirine vaginal ring. If it is approved, the monthly dapivirine ring would be the first biomedical HIV prevention method developed specifically for women. Such a device would provide a prevention option besides oral preexposure prophylaxis (PrEP), which consists of the anti-HIV drugs emtricitabine and tenofovir disoproxil fumarate (Truvada). Truvada is the only medication currently approved for HIV PrEP; oral PrEP is being rolled out in many countries for HIV prevention.

In 2016, researchers with MTN and IPM reported the results of two Phase III trials assessing the efficacy of the monthly ring. The findings indicated it was effective in preventing HIV infection. The results suggested that the overall risk of HIV infection was reduced by about 30% in the two studies. Increased levels of protection were noted in women who used the ring with the most regularity.[3,4] The two trials involved 4,588 women in Malawi, Uganda, South Africa, and Zimbabwe — countries where rates of HIV infection in women remain among the highest in the world. (Contraceptive Technology Update *reported on the research; see the May 2016 article, "Two Studies Show Monthly Vaginal Ring Protects Women Against HIV," http://bit.ly/2twpOHi.*)

At the recent 2018 HIV Research for Prevention conference in Madrid, researchers reported minimal risk of drug resistance with use of the dapivirine ring.[5] Scientists used both standard genotyping and next-generation sequencing to examine plasma samples from women who acquired HIV during participation in the ASPIRE Phase III trial. Results indicate that among women who acquired HIV in the trial, relatively few had evidence of resistant virus, particularly virus resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs).[5] Dapivirine is classified as an NNRTI.

"We looked pretty hard, using the most sensitive tests that can detect genetic changes in thousands of individual viruses from a single infected person," says **Urvi Parikh**, PhD, associate director of the Microbicide Trials Network Laboratory Center Virology and Pharmacodynamics Core at the University of Pittsburgh. "In this study, we found that the risk of dapivirine-related resistance in someone using the dapivirine ring was the same as the risk in someone who wasn't using the ring." ■

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Research Strides May Offer Keys to Battling Gonorrhea

What will it take to help clinicians stem the rising tide of gonorrhea? Public health reports indicate the incidence of gonorrhea in the United States has jumped by 67% from 2013 through 2017, while the antimicrobial resistance of *Neisseria gonorrhoeae* has increased.[1,2]

Potential tools to fight gonorrhea are in development. Researchers are investigating a rapid test that not only checks for gonorrhea infection, but also signals if a particular strain is antibiotic-resistant. On another front, scientists report that one dose of a developmental oral antibiotic proves effective in treating uncomplicated genital infections caused by gonorrhea.[3]

The National Institutes of Health recently awarded a $5.1 million grant to a team of Johns Hopkins University (JHU) scientists to develop a device that not only rapidly tests for gonorrhea, but detects if a bacterial strain is resistant to antibiotics. **Jeff Wang**, PhD, a professor in JHU's Whiting School of Engineering's Department of Mechanical Engineering and member of the school's Institute for NanoBioTechnology, is heading the investigation. Researchers from JHU's Whiting School of Engineering and School of Medicine, the World Health Organization, GE Global Research, and Stanford University also are involved in the inquiry.

"Our diagnostic tool will help physicians personalize treatments to individual infections rather than using the current uniform approach, which is thought to significantly influence antimicrobial resistance," Wang said in a press statement.

The device will perform an analysis of the organism's observable characteristics and behaviors, and look at specific DNA markers to assess its susceptibility to antimicrobials, Wang explains. The analysis results will determine whether a patient has an infection, which medications would work best to treat the infection, and the minimum amount of medication needed for treatment, he said. The device now in development will cut testing time to one hour or less, meaning patients can get their results quickly and can begin treatment almost immediately.

Charlotte Gaydos, DrPH, MPH, MS, professor of medicine in the Division of Infectious Diseases at the Johns Hopkins University School of Medicine, calls the device a "game changer." By receiving fast results and understanding resistance susceptibility, clinicians can create more precise therapy, she noted in a press statement. Testing also can determine whether antibiotics that are not currently listed in guidance, but that were recommended by the Centers for Disease Control previously, will work. This will allow clinicians to reserve stronger medications for cases in which they are truly necessary, she explained.

New Antibiotic Explored

Just-published research from a Phase II multicenter clinical trial indicated that zoliflodacin, an investigational oral antibiotic, was tolerated well and cured most uncomplicated gonorrhea cases.[3] Zoliflodacin is a new type of orally administered antibiotic that works differently from currently available

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Researchers are investigating a rapid test that not only checks for gonorrhea infection, but also signals if a particular strain is antibiotic-resistant. On another front, scientists report that one dose of a developmental oral antibiotic proves effective in treating uncomplicated genital infections caused by gonorrhea.

- Scientists at Johns Hopkins University are developing a device that not only tests for gonorrhea rapidly, but also detects whether a particular bacterial strain is resistant to antibiotics.
- Research data indicate that zoliflodacin, an investigational antibiotic, is tolerated well and provides successful treatment of most cases of uncomplicated gonorrhea. Zoliflodacin is a new type of orally administered antibiotic that works differently from currently available medications to inhibit DNA synthesis.

medications to inhibit DNA synthesis.

The trial, conducted between November 2014 and December 2015, involved 179 participants (167 men and 12 non-pregnant women) from New Orleans; Seattle; Indianapolis; Birmingham, AL; and Durham, NC. Patients ranged in age from 18 to 55 years. The study participants had symptoms of uncomplicated urogenital gonorrhea, had urogenital gonorrhea that was untreated, or had sexual contact with a person who had gonorrhea within 14 days before study enrollment. The researchers randomized the participants to receive one 2- or 3-gram dose of zoliflodacin orally or an injected 500-mg dose of ceftriaxone. Six days after treatment, researchers evaluated 117 per-protocol participants. Among these participants, 98% (48 of 49 participants) of the ones who received 2 g of zoliflodacin, 100% (47 of 47 participants) of those who received 3 g of zoliflodacin, and all (21 of 21) of those in the ceftriaxone group experienced cure of their urogenital gonorrhea, according to culture results. Although the investigational drug cured all of the rectal gonorrheal infections (4 of 4 participants receiving the 2-g dose and 6 of 6 participants receiving the 3-g dose), it did not prove as effective against gonorrhea infections of the throat, scientists report.[3]

The U.S. Food and Drug Administration (FDA) has given zoliflodacin fast-track status for development as an orally administered treatment for gonococcal infections. Investigators plan to initiate Phase III testing of the drug in the Netherlands, South Africa, Thailand, and the United States in 2019.

It is "imperative" to develop an affordable, effective oral treatment option for gonorrhea, as the bacteria has become more resistant to antibiotics, says **Jeanne Marrazzo**, MD, division director of the University of Alabama at Birmingham Division of Infectious Diseases. Marrazzo served as a co-author of the current paper.

"As researchers and clinicians, we are excited that zoliflodacin offers a viable treatment option for the majority of uncomplicated urogenital and rectal gonococcal infections," said Marrazzo in a press statement. ■

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Injectable Implant Focus of HIV Treatment/ Prevention Research

When it comes to HIV/AIDS, getting patients to adhere to antiretroviral therapy remains a challenge for clinicians. Studies indicate adherence varies between 27% and 80% across different populations, compared with the required level of 95%.[1]

Researchers with the University of North Carolina at Chapel Hill (UNC-CH) and the Centers for Disease Control and Prevention are examining a new drug delivery system that uses dolutegravir, an established HIV drug, in a potential long-acting treatment and prevention system.[2] The system has been tested in animal models.

Once the formulation of an anti-HIV drug, a polymer, and a solvent is injected under the skin, the three-component liquid solidifies into an implant. Drug release occurs as the polymer in the implant slowly degrades.

"Our study found that the formulation delivered the drug effectively, and the implants were well tolerated with little or no sign of toxicity, for five months," said **Martina Kovarova**, PhD, co-principal investigator of the study, assistant professor of infectious diseases at UNC-Chapel Hill, and a member of the UNC Center for AIDS Research, in a press statement. "It seems to us to be the ideal drug formulation for the prevention and treatment of HIV and AIDS."

The implant can be removed in a quick, safe manner by making a small skin incision at the implant site, researchers note. This offers a safety advantage if a patient develops an adverse reaction or becomes pregnant while the implant is in place, noted study co-author **Rahima Benhabbour**, PhD, co-principal investigator in the study and an assistant professor in the UNC-NCSU Joint Department of Biomedical Engineering.

"Adherence to medications is essential for treatment success," said **J. Victor Garcia**, PhD, co-investigator of the study and Oliver Smithies

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Researchers with the University of North Carolina at Chapel Hill and the Centers for Disease Control and Prevention are examining a new drug delivery system that uses dolutegravir, an established HIV drug, in a potential long-acting treatment and prevention system. The system has been tested in animal models.

- The injectable formulation includes the anti-HIV drug, a polymer, and a solvent. Once injected under the skin, the three-component liquid solidifies into an implant. Drug release occurs as the polymer in the implant slowly degrades.
- Other implant options in development include a drug delivery device to help prevent both HIV and pregnancy, as well as a matchstick-sized silicone device that houses the antiretroviral drug tenofovir alafenamide.

Investigator at UNC-Chapel Hill School of Medicine. "This is clearly important for HIV/AIDS treatment and prevention, but also for the treatment of many other chronic conditions like mental illnesses, hypertension and diabetes, where this technology might have applications."

The UNC researchers recently received the award of a five-year, $3.8 million grant from the National Institute of Allergy and Infectious Diseases to build upon their current research. The National Institutes of Health funded the initial investigation.

"Our long-term goal for this collaborative is to develop a delivery system for long-acting therapy and PrEP [pre-exposure prophylaxis] that can offer durable and sustained viral suppression and protection from HIV transmission while providing flexibility in the choice of active ingredient, high efficacy of HIV inhibition, and increased user compliance," said **Angela Wahl**, PhD, assistant professor of infectious diseases at the UNC School of Medicine.

Additional Implant Options in Development

What other implant options are in development? The U.S. Agency for International Development has awarded RTI International, a Research Triangle Park, NC-based nonprofit organization, a $4.8 million cooperative agreement to develop a drug delivery device to help prevent both HIV and pregnancy. The grant, issued in 2017, was made through the U.S. President's Emergency Plan for AIDS Relief. In a three-year program, the RTI-lead team is scheduled to develop an implant that provides long-acting prevention of pregnancy and HIV. Known as the Subcutaneous Contraceptive and HIV Implant Engineered for Long-Acting Delivery (SCHIELD), the device will include dual protection while offering the advantages of being discreet, simple to administer, and biodegradable.

RTI scientists also are collaborating with academic partners to develop a similar long-acting implant for delivery of antiretroviral therapy. Made of polycaprolactone material, the implant is biodegradable but otherwise remains retrievable during the drug delivery phase. The implant currently is in preclinical studies, and research indicates sustained drug release up to three months in the rabbit animal model.[3]

A matchstick-sized silicone device that houses tenofovir alafenamide is under development by the Oak Crest Institute of Science in Monrovia, CA. Research in beagle dogs indicates successful delivery of the study drug.[4]

Northwestern University scientists are investigating implantable PrEP systems. Through the Sustained Long-Acting Protection from HIV (SLAP HIV) program, researchers are working toward developing and testing a long-acting drug delivery system of either cabotegravir or tenofovir alafenamide fumarate.

Scientists will examine reservoir implants, degradable implants, and controlled-release injectables as vehicles for drug delivery.

Scientists at Houston Methodist Research Institute are investigating a refillable silicon-based nanochannel device to deliver HIV/AIDS drugs. Preclinical studies of the refillable implant indicate positive results.[5] ■

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WASHINGTON WATCH

Elections Bring Renewed Challenges for Reproductive Rights

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The November 2018 elections shook up both Washington, DC, and the political landscape for sexual and reproductive health and rights. Meanwhile, the Trump administration did not wait even a full day after the elections before renewing its attacks on health insurance coverage of abortion and contraception and on the Title X family planning program.

With the House of Representatives changing hands, supporters of reproductive rights in that chamber now will be positioned to better protect against anti-abortion and anti-contraception policies. They will have more leverage to block legislative attacks on perennial targets, including the Affordable Care Act (ACA), Medicaid, Title X, Planned Parenthood, abortion rights, and contraceptive coverage. The new House leadership also is gearing up to engage in oversight of the Trump administration on a range of issues, which will include holding public hearings, subpoenaing testimony from administrative officials, and demanding the release of relevant administrative records.

By contrast, the Senate leadership will be working with an increased majority and will have new opportunities to advance its socially conservative agenda. Notably, Republican Sens. Susan Collins (ME) and Lisa Murkowski (AK) likely will have less sway than before; the pair frequently have broken with other members of their party in voting to support family planning programs at home and abroad, protect abortion rights, maintain federal funding for Planned Parenthood, and uphold the ACA. Moreover, the larger majority will make it easier for President Trump to secure Senate confirmation of cabinet members, other high-ranking federal officials, and federal judges, potentially including new members of the Supreme Court. That will make it easier for the president to advance his agenda over the next two years and, through the judiciary, for many years to come.

The day after the election, the Trump administration announced a proposed rule further restricting private abortion coverage in the ACA marketplaces.[1,2] Twenty-six states bar abortion coverage in marketplace plans, but in the remaining states, marketplace plans can cover abortion in cases beyond rape, incest, or life endangerment if they take required steps to ensure the procedure is paid for with private premium dollars, and not federal tax credits and subsidies. (*Read more; see the* Contraceptive Technology Update *November 2018 column, "Conservatives Work to Bar Private Coverage of Abortion," at https://bit.ly/2DyAVYB.*) The new rule would make those steps more burdensome for insurers and consumers by requiring two entirely separate monthly bills: one for the bulk of the health insurance policy, and a second for the minimal charge associated with abortion coverage. (Currently, insurers can separate those two payments on their own, without requiring consumers to do anything.) The proposed rule would create a situation in which consumers could risk losing

their insurance coverage altogether if they misunderstand and fail to pay the separate fee for abortion coverage. This possibility and the additional costs and burdens of compliance may lead some insurers to drop abortion coverage entirely.

On the same day, the Trump administration also finalized a pair of regulations that vastly expand organizations' ability to deny employees, students, and dependents insurance coverage for contraceptive counseling, services, and supplies.[3] The rules are substantively the same as the interim rules issued in October 2017. (*Get more information; see the January 2018 column, "New Rules Undermine Federal Contraceptive Coverage Guarantee," at https://bit.ly/2Q76RJZ.*) As before, the ACA's contraceptive coverage guarantee is still in effect, but these regulations expand the pool of entities that may opt out, allowing any nongovernmental employer or university to claim a religious exemption or, in most cases, a moral exemption. The regulations fail to offer guardrails to prevent abuse, such as standards for how an organization might establish that it has a religious or moral objection, or a mechanism for employees or students to challenge that claim. Several states and organizations challenged the interim rules last year, and courts in California and Pennsylvania have enjoined them nationwide. As of mid-November 2018, it is not yet clear how the final rules will complicate those and other ongoing lawsuits, but it does seem clear that the lawsuits will continue.

Also on Nov. 7, 2018, the Trump administration released the FY 2019 funding opportunity announcement for Title X family planning service providers.[4] As was the case with the previous funding announcement, the administration seems to be advancing some of its ideological priorities within the Title X program. (*Read more about the issue; see the July 2018 column, "With Funding Announcement, Trump Begins Reshaping Title X," at https://bit.ly/2FvmWFj.*) This includes potentially reshaping the Title X provider network by disadvantaging reproductive health-focused providers and leaving the door open for sites like anti-abortion counseling centers; pushing harmful abstinence-only-until-marriage messages to adolescents; and potentially interfering with young people's ability to obtain care confidentially. Unlike in the previous funding announcement, the administration is directly addressing the need for Title X projects to offer clinical services and hormonal methods of contraception, and to adhere to national guidelines for the provision of high-quality family planning services put forward by the Centers for Disease Control and Prevention and the Office of Population Affairs (which administers Title X). Applications were scheduled to be due Jan. 14, 2019, with projects slated to start April 1. ■

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COMING IN FUTURE MONTHS

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- Provide culturally competent care
- How can your practice be "PrEP-ared"?
- Investigating menstrual cup's role in preventing infection

CONTRACEPTIVE TECHNOLOGY UPDATE®

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CME/CE QUESTIONS

1. What is the new name for the female condom?

a. Internal condom
b. Woman-based condom
c. Internal sheath
d. Guantone

2. What is the expanded age range for the nine-valent human papillomavirus vaccine approved by the Food and Drug Administration?

a. Women and men ages 27 through 35
b. Women and men ages 27 through 45
c. Women and men ages 27 through 50
d. Women and men ages 27 through 55

3. What are the two drugs in the vaginal ring under study by the International Partnership for Microbicides and the Microbicide Trials Network?

a. Dapivirine and norgestimate
b. Tenofovir disoproxil fumarate and levonorgestrel
c. Dapivirine and levonorgestrel
d. Dolutegravir and levonorgestrel

4. What is the name of the oral antibiotic that scientists are studying as a potential treatment for uncomplicated gonorrhea?

a. Amphotericin
b. Terbinafine
c. Mefloquine
d. Zoliflodacin

CME/CE OBJECTIVES

After reading *Contraceptive Technology Update*, the participant will be able to:

1. identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services;
2. describe how those issues affect services and patient care;
3. integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
4. provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.