AMERICAN HEALTH CONSULTANTS®

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

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AUGUST 2001

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News flash: Add new 25-mcg Cyclessa to triphasic oral contraceptive options

Pill represents lowest estrogen dose in a triphasic pill available in U.S.

When reviewing the choices in triphasic oral contraceptives (OCs), providers now can add another option: Cyclessa from Organon of West Orange, NJ. The pill represents the lowest estrogen dose available in a triphasic pill.

Cyclessa consists of 25 mcg of ethinyl estradiol (EE) per day for 21 days. The daily progestin dose is 100 mcg of desogestrel for days 1-7, 125 mcg for days 8-14, and 150 mcg for days 15-21. The last seven pills in the 28-day blister package are placebo pills.

"The 25-mcg ethinyl estradiol with desogestrel pill is a low-dose triphasic oral contraceptive that offers women yet another choice of oral contraceptives," says **Sharon Schnare**, RN, FNP, CNM, MSN, women's health consultant and clinician with the Seattle King County Health Department in women's and adolescent health care and the International District Community Health Center in Seattle. "With current studies showing low-dose oral contraceptives having similar health benefits as higher-estrogen dose pills, this offers a lower-dose option pill for women."[1]

While Organon received Food and Drug Administration approval for Cyclessa in December 2000, it chose to make its announcement during the June 2001 consumer launch to coincide with the stocking of Cyclessa on retail pharmacy shelves, says **Nancy Alexander**, PhD, director of

EXECUTIVE SUMMARY

Cyclessa, an oral contraceptive (OC) from Organon, is the latest addition to the triphasic pill choices available to American women. The pill represents the lowest estrogen dose available in a triphasic pill.

- Cyclessa consists of 25 mcg of ethinyl estradiol per day for 21 days. The last seven pills in the 28-day blister package are placebo pills.
- In clinical trials, Cyclessa users reported less breakthrough bleeding and spotting than women who were using a higher estrogen-dose triphasic OC. Contraceptive efficacy was comparable to the higher estrogen-dose pill.

contraception at Organon. The delay in announcement allowed the company to ensure that Cyclessa is covered by many health insurance plans, she states. Cost of the new pill is comparable to other currently marketed brands, says Alexander.

Add to triphasic list

Cyclessa is making its first appearance in the United States and is not yet available in other countries, confirms Alexander. It joins the following U.S.-marketed triphasic pills: Triphasil (Wyeth-Ayerst Laboratories, Philadelphia), Tri-Levelen (Berlex Laboratories, Montville, NJ), Trivora and Tri-Norinyl (Watson Laboratories, Corona, CA), Ortho-Novum 7/7/7 and Ortho Tri-Cyclen (Ortho-McNeil Pharmaceuticals, Raritan, NJ). Estrostep (Parke-Davis, Morris Plains, NJ) uses a triphasic dose of EE (20, 30, and 35 mcg) with a steady 1 mg dose of the progestin norethindrone acetate.

Ortho Tri-Cyclen, Ortho-Novum 7/7/7, and Tri-Norinyl contain 35 mcg of EE, with Triphasil, Tri-Levelen, and Trivora formulated with a 30 mcg EE dose. The progestins in the triphasic list include norgestimate (Ortho Tri-Cyclen), levonorgestrel (Triphasil, Tri-Levelen, Trivora), and norethindrone acetate (Ortho-Novum 7/7/7, Tri-Norinyl).

A potential advantage of triphasic OCs is the lowering of overall monthly progestin dose while maintaining contraceptive efficacy and reducing cycle control problems such as breakthrough bleeding/spotting, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. Kaunitz authored the report of the contraceptive safety and efficacy trial for Cyclessa.[2]

"The availability of a reduced estrogen-dose pill with excellent cycle control represents a positive new oral contraceptive choice," states Kaunitz.

For women whose providers wish to prescribe a triphasic pill, Cyclessa's lower dose of estrogen makes it a suitable choice for both first-start patients and those switching from other pills, says Alexander. The pill joins Organon's other two OCs, Desogen and Mircette, which also use EE and desogestrel in their formulations.

Review research results

Two identical multicenter, open-label, randomized, parallel group, comparative Phase III six-cycle trials were used to analyze the contraceptive efficacy, cycle control, and safety of Cyclessa. The trials compared Cyclessa against another triphasic, Ortho-Novum 7/7/7.

A total of 5,654 women were enrolled in both controlled trials. Early discontinuation rates (18.4%) were identical for the Cyclessa and Ortho-Novum 7/7/7 group.

In these two trials, which involved a total of 29,130 cycles of exposure, the contraceptive efficacy of Cyclessa was equivalent to that of Ortho-Novum 7/7/7, according to the researchers.

Four pregnancies were reported in the group of 2,353 women who took Cyclessa during all six cycles with proper compliance and used no backup method; eight pregnancies were recorded in the 2,393 women who took Ortho-Novum 7/7/7. The Pearl Index was 0.51 for the Cyclessa group and 1.00 for the Ortho-Novum group, a difference that was not statistically significant. The six-cycle life table cumulative pregnancy rate for Cyclessa was estimated as 0.0051; for Ortho-Novum 7/7/7, it was 0.0039.

Cycle control a plus

In the clinical trial, Cyclessa users reported less breakthrough bleeding and spotting than women who used Ortho-Novum 7/7/7. For each of the months of the study, the incidence of breakthrough bleeding/spotting was lower in the Cyclessa group than the Ortho-Novum 7/7/7 group.

Generally, the incidences of breakthrough bleeding and spotting are reported to increase with lower estrogen doses; however, Cyclessa provided improved cycle control in comparison with Ortho-Novum 7/7/7, states Kaunitz in the clinical trial report.

COMING IN FUTURE MONTHS

- Gestodene: Will U.S. see progestin in pills?
- Pharmacy Access Partnership speeds EC access
- Expanding access to family planning clinics
- Can the IUD be resurrected?
- Medical abortion update: What's the status in the U.S.?

RESOURCE

For more information on Cyclessa, contact:
- **Organon**, 375 Mount Pleasant Ave., West Orange, NJ 07052. Telephone: (800) 241-8812 or (973) 325-4729. Web: www.organoninc.com.

There was significantly less weight gain and less increase in body mass index in the Cyclessa group, according to the clinical trial findings.

Michael Rosenberg, MD, MPH, clinical professor of obstetrics and gynecology at the school of medicine and adjunct professor of epidemiology at the school of public health at the University of North Carolina at Chapel Hill, says, "As we reduce the dose of estrogen, the question is the balance between cycle control and estrogenic symptoms, from a user perspective. Both of these are among the most common side effects and directly related to user satisfaction and continuation rates." Rosenberg is president of Health Decisions, a Chapel Hill private research firm specializing in reproductive health.

A randomized, open-label multicenter clinical trial compared Alesse (a 20-mcg EE / levonorgestrel pill from Wyeth-Ayerst Laboratories), Mircette (a 20-mcg EE / desogestrel pill from Organon) and Ortho Tri-Cyclen (a 35-mcg EE / norgestimate pill).[3] Bloating, breast tenderness, and nausea were approximately 50% more common in women using the 35-mcg pill compared to those taking the 20-mcg pills. Cycle control was similar in all products, although during the first two cycles among starters, users of Mircette and Ortho Tri-Cyclen exhibited better cycle control than Alesse users.

The movement toward lower estrogen-containing OCs places renewed emphasis on proper use of OCs — taking a pill every day, preferably at the same time — and on the need for proper counseling to that effect, states Rosenberg.

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Research gives nod to lower-dose HRT

How many postmenopausal women in your care have begun hormone replacement therapy (HRT), only to discontinue its use due to such initial side effects as irregular bleeding? Recent research now indicates that new lower-dose forms of HRT are just as effective as commonly prescribed doses in relieving vasomotor symptoms and improving vaginal atrophy, while producing higher rates of amenorrhea.[1,2]

About a third of U.S. women over age 50 take some form of HRT to relieve menopausal symptoms or to reduce risk of osteoporosis.[3] Side effects include vaginal bleeding, the top reason for HRT discontinuation.[3]

Based on the research, Wyeth-Ayerst Laboratories in Philadelphia has moved to introduce a lower-dose version of Prempro, its combined HRT drug. Prempro contains 0.625 mg of conjugated equine estrogens (CEE) and 2.5 mg of medroxyprogesterone acetate (MPA).

According to Wyeth-Ayerst spokeswoman **Audrey Ashby**, the company received an approvable letter from the Food and Drug Administration in April 2001. The letter serves as an indication that the agency is prepared to approve the company's application upon the satisfaction of specified conditions.

"Discussions with the agency are ongoing," states Ashby. "Based on the current status, we are projecting a third-quarter launch of Prempro 0.45 [conjugated estrogens] / 1.5 MPA."

More choices in terms of estrogen dose for combination formulations would be a welcome

EXECUTIVE SUMMARY

The first two articles from a two-year company-sponsored clinical trial of the safety and efficacy of lower-dose regimens of hormone replacement therapy (HRT) in postmenopausal women suggest that the lower doses are as effective in relieving vasomotor symptoms and improving vaginal atrophy, while producing higher rates of amenorrhea.
- Side effects of HRT include vaginal bleeding, the top reason for HRT discontinuation.
- Based on its research, Wyeth-Ayerst is moving ahead to introduce a lower-dose version of Prempro, its combined HRT drug.

addition to therapy, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center in Jacksonville.

Oral and transdermal estrogen replacement therapy formulations are available in a wide array of doses, notes Kaunitz. In contrast, current combination estrogen-progestin HRT formulations are available in only one dose of estrogen.

Examine the results

The two new papers lead off a series of published research from the Women's Health, Osteoporosis, Progestin, Estrogen study, a two-year, double-blind, placebo-controlled clinical trial supported by Wyeth-Ayerst.

The study looked at 2,673 postmenopausal women who still had their uterus intact. The design of the study included a one-year basic study focused on menopausal symptoms, endometrial histology, and bleeding profiles, and a two-year substudy that examined bone density and turnover, lipoproteins, and carbohydrate metabolism.

Papers on endometrial histology and plasma lipoproteins are scheduled to be published by summer's end, with research following in the next two to three months on bone density, according to **Wulf Utian**, MD, PhD, lead author of the vasomotor symptoms paper. ***(Contraceptive Technology Update* will report results of these papers in upcoming issues.)** He serves as executive director of the Mayfield Heights, OH-based North American Menopause Society.

In the study, patients received for one year (13 cycles; in milligrams per day) CEE, 0.625; CEE, 0.625 and MPA, 2.5; CEE, 0.45; CEE, 0.45 and MPA, 2.5; CEE, 0.45 and MPA, 1.5; CEE, 0.3; CEE, 0.3 and MPA, 1.5; or placebo.

In the vasomotor symptom / vaginal atrophy paper, researchers compared the frequency and intensity of hot flashes, as well as charted changes in the vaginal maturation index, a measurement of vaginal atrophy. The lower doses appeared to be just as effective as the most commonly prescribed doses, and they should be considered as initial treatment options for a majority of women, researchers conclude.

In the endometrial bleeding paper, researchers analyzed bleeding data from the eight treatment groups. They found that the lower doses of CEE and MPA produced higher rates of amenorrhea than the most commonly prescribed doses, especially during the earlier cycles of therapy. The results suggest that lower doses may be the appropriate choice of therapy in newly menopausal patients, conclude the researchers.

"The major reason for stopping taking HRT in postmenopausal women is the occurrence of bleeding," states the paper's lead author, **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical School in Norfolk. "And anything that one can do to reduce this side effect would help with compliance in women staying on the HRT." **(See patients' handouts on HRT in Spanish and English enclosed in this issue.)**

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Contraceptive patch, ring: In U.S. by 2001?

For those women who have difficulty remembering to take a daily pill, two new contraceptive options — a transdermal patch and a vaginal ring — may be available by the end of 2001, if approved by the Food and Drug Administration (FDA).

Research has just been published on the Ortho Evra contraceptive patch, developed by the R.W. Johnson Pharmaceutical Research Institute in Raritan, NJ, and the NuvaRing contraceptive vaginal ring, to be marketed in the United States by Organon in West Orange, NJ.[1,2]

According to Ortho-McNeil Pharmaceuticals in Raritan, NJ, which will market the Ortho patch, the product's New Drug Application was filed with the FDA in December 2000 and is under review. **(Read more about the dosing trial and patient compliance experience with the patch in the March 2001 issue of *Contraceptive***

EXECUTIVE SUMMARY

A transdermal patch and a vaginal ring may be available by the end of the year, if approval is received from the Food and Drug Administration.

- Just-released research findings indicate that the Ortho Evra patch, developed by the R.W. Johnson Pharmaceutical Research Institute, is comparable to the Pill in contraceptive efficacy and cycle control.
- The NuvaRing vaginal ring from Organon has received marketing approval in several European countries. The ring, which carries a combination of the progestin etonogestrel and the estrogen ethinyl estradiol, is designed to be worn three weeks, then removed for one week.

***Technology Update*, p. 29.)**

The NuvaRing contraceptive vaginal ring also is moving through FDA channels, states **Nancy Alexander**, PhD, director of contraception at Organon. The device has just received approval, via the European mutual recognition procedure, for Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Norway, Portugal, Spain, and Sweden, she says.

Organon plans a "clinical experience" program involving some 6,000 obstetrician / gynecologists prior to the commercial launch of the NuvaRing, says Alexander. The program will allow providers to become comfortable with the new method prior to prescription, she states.

Look for more research on the NuvaRing to be published in the near future, reports Alexander. ***(Contraceptive Technology Update* will report results of these papers in upcoming issues.)**

Ovarian suppression compares with OCs

In the currently published paper, a small study examining ovulation function, findings indicate that the NuvaRing completely inhibited ovulation throughout the normal three-week period and a two-week extended period of use.[2] Ovarian suppression was comparable to that with a combination oral contraceptive (OC) containing ethinyl estradiol and desogestrel, according to the study.

The ring, which carries a combination of the progestin etonogestrel and the estrogen ethinyl estradiol, is designed to be worn three weeks, then removed for one week. In a separate study, results indicate that the device offers good cycle control with favorable patient compliance.[3]

Taking a daily pill can be a problem for many women. In a study evaluating consistency of use of OCs, 47% of users missed one or more pills per cycle, and 22% missed two or more doses.[4]

The contraceptive vaginal ring represents a major development in terms of options for women, says **Michael Rosenberg**, MD, MPH, clinical professor of obstetrics and gynecology at the school of medicine and adjunct professor of epidemiology at the school of public health, both at the University of North Carolina at Chapel Hill, and president of Health Decisions, a Chapel Hill private research firm specializing in reproductive health.

By being able to insert the ring and remove it 21 days later, the need is removed for taking a daily pill, observes Rosenberg.

"The biggest compliance problem with the ring — and a minor one at that — is remembering to remove it after day 21," notes Rosenberg.

The ease of use of the Ortho Evra patch may be its greatest strength, comments **William Koltun**, MD, director of the Medical Center for Clinical Research in San Diego and co-author of the efficacy / cycle control paper.

"The Ortho Evra patch requires essentially three actions by the patient during the course of a 30-day period, vs. the birth control pill, which requires 28 different actions, taking a pill daily," Koltun remarks. "I think that its safety and efficacy are equal to the birth control pill, and if you can reduce the frequency of things that people have to do to guarantee efficacy, you will provide a product with which people feel more comfortable."

Patch effective as Pill

The Ortho Evra patch relies on the progestin / estrogen combination of norelgestromin and ethinyl estradiol for its contraceptive effectiveness. It is designed to be worn on several areas of a woman's body, but most typically it is placed on the lower abdomen or buttocks. The patch is worn for one week at a time and is changed on the same day of the week three times a month. The fourth week is patch-free.

In the study analyzing the contraceptive efficacy and cycle control of the patch vs. an OC, the patch was found comparable to the Pill in both areas.[1] The randomized, multicenter study followed 1,417 women ages 18-45 for up to 13 monthly cycles.

In looking at contraceptive efficacy, researchers

determined that the overall and method-failure Pearl Indexes were numerically lower in the patch group, although the differences between the treatments were not statistically different. Four method-failure pregnancies and one user-failure pregnancy occurred among 811 women treated for 5,240 cycles in the patch group; in the OC group, four method-failure pregnancies and three user-failure pregnancies occurred among 605 women treated for 4,167 cycles.

As for cycle control, breakthrough bleeding and/or spotting was significantly higher only in the first two cycles in the patch group. The incidence of breakthrough bleeding alone was comparable between treatments in all cycles, state the investigators.

Compliance with the dosing schedule of the patch was better than that of the OC, the study indicates. The observation that improved compliance may result in lower typical-use contraceptive failure rates needs to be confirmed in larger studies, the researchers conclude.

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New generic OCs now on the pharmacy shelves

Generic equivalents of three oral contraceptives (OCs), including the therapeutic equivalent of a popular 20-mcg pill, are now available on pharmacy shelves.

Duramed Pharmaceuticals of Cincinnati began shipment of its Aviane-28 Tablets in May following the approval of its Abbreviated New Drug Application by the Food and Drug Administration (FDA), according to **Jeff Zurcher**, director of corporate communications. With 20 mcg of ethinyl estradiol and 100 mcg of the progestin levonorgestrel, Aviane is the first generic product deemed bioequivalent to and therapeutically interchangeable with the OC Alesse, which is marketed by Wyeth-Ayerst Laboratories of Philadelphia, according to Duramed.

EXECUTIVE SUMMARY

Three new generic oral contraceptives (OCs) are now available.

- Duramed Pharmaceuticals is marketing Aviane-28 OC. With 20 mcg of ethinyl estradiol and 100 mcg of levonorgestrel, the OC contains the same hormone levels found in Alesse.
- Barr Laboratories is introducing generic equivalent versions of Ortho-Novum 1/35 and Modicon-28. Nortrel 1/35 is offered in both 21-day and 28-day regimens, with Nortrel 0.5/35 in a 28-day regimen.

Barr Laboratories of Pomona, NY, was set to begin distribution at the end of June of its generic equivalent versions of Ortho-Novum 1/35 and Modicon-28, two pills from Raritan, NJ-based Ortho-McNeil Pharmaceuticals, reports **Carol Cox**, Barr Laboratories spokesman. The company plans to market both strengths as branded generics using the Nortrel trademark, launching Nortrel 1/35 in a 21-day regimen and a 28-day regimen, and Nortrel 0.5/35 in a 28-day regimen.

Look at low-dose option

The addition of Aviane adds another 20-mcg ethinyl estradiol pill to the available options for U.S. women. These alternatives include Alesse, Levlite from Berlex Laboratories of Montville, NJ, Loestrin 1/20 from Parke-Davis of Morris Plains, NJ, and Mircette from Organon of West Orange, NJ.

Levlite, like Alesse and Aviane, contains 100 mcg of levonorgestrel, while Loestrin is formulated with 1 mg of norethindrone acetate. Mircette differs in both its dosing regimen and progestin. It relies on 21 days of 20 mcg of ethinyl estradiol and 150 mcg of the progestin desogestrel, followed by two days of placebo pills, completed by five days of 10-mcg pills of ethinyl estradiol. **(More information on these pills can be found in the following issues of *Contraceptive Technology Update*: Levlite, November 1998, p. 145; Mircette, July 1998, p. 85; Alesse, August 1997, p. 93.)**

Results of the 2000 *CTU* Contraception Survey indicate that 20-mcg pills are gaining ground on the top choice, Ortho Tri-Cyclen, a 35-mcg ethinyl estradiol/norgestimate phasic pill from Ortho-McNeil Pharmaceuticals. **(See results of the 2001 survey in next month's issue of *CTU*.)**

According to the 2000 survey results, Alesse and Mircette moved up to capture more than 21% of nonformulary responses. The two pills accounted for less than 10% of 1999 responses in the same category. **(See the September 2000 issue of *CTU* for more survey results, and the June 2000 issue, p. 72, for an overview of the trend toward 20-mcg pills.)**

Aviane joins Apri

Aviane is Duramed's second entry into the oral contraceptive market and joins Apri, which was launched in the fourth quarter of 1999. With 30 mcg of ethinyl estradiol and 150 mcg of desogestrel, Apri is the first substitutable product equivalent to Ortho-McNeil Pharmaceutical's Ortho-Cept and Organon's Desogen. ***(CTU* reviewed the FDA approval of Apri in its February 2000 issue, p. 19.)** The company also markets its own branded estrogen replacement therapy product, Cenestin (synthetic conjugated estrogens), as well as other generic products.

As with Apri, Duramed will be marketing Aviane as a value brand, meaning that the OC can be written as a prescription by providers and/or substituted for the brand product by pharmacists, according to **Jeffrey Arington**, Duramed president and chief operating officer. The company has additional Abbreviated New Drug Applications for oral contraceptives on file with the FDA, says Zurcher.

First two OCs from Barr

Barr Laboratories' Nortrel 1/35 is a substitutable product equivalent to Ortho-Novum 1/35, containing 1 mg of norethindrone and 35 mcg of ethinyl estradiol. Nortrel 0.5/35 is the generic equivalent of Modicon-28 and offers 0.5 mg of norethindrone and 35 mcg of ethinyl estradiol.

The two new Nortrel pills represent the company's first entrants in the oral contraceptive market, says Cox. The company is focusing its sales and marketing efforts on wholesalers and retailers in moving the two OCs as value brands, she states.

"Over the next two years, Barr expects to build a complete line of generic oral contraceptive products that will compete in the $2 billion oral contraceptive marketplace," says **Bruce Downey**, company chairman and CEO. "We believe that our contraceptive line will offer women less expensive alternatives as they address their family planning needs."

The company is now in Phase III clinical trials with its own pill, Seasonale. The OC uses a patented 84-day dosing regimen, if approved by the FDA, would introduce the first four-periods-per-year pill in the United States. **(See the May 1999 issue of *CTU*, p. 51, for more information on Seasonale.)**

Clinical studies on the drug should be finished by January 2002, and its New Drug Application is projected to be filed with the FDA in spring or summer of the same year, says Cox. If the OC does receive FDA clearance, it is projected to be available between May and September of 2003, she states. ■

RESOURCES

For more information on the Nortrel line of OCs, contact:

- **Barr Laboratories Inc.,** 2 Quaker Road, P.O. Box 2900, Pomona, NY 10970-0519. Telephone: (800) 227-7522 (BARRLAB). Web: www.barrlabs.com.

For more information on Aviane, contact:

- **Duramed Pharmaceuticals**, 5040 Duramed Drive, Cincinnati, OH 45213. Telephone: (800) 543-8338. Web: www.duramed.com.

Court ruling advances contraceptive coverage

The push for insurance coverage of prescription contraceptives has moved forward with a federal court ruling that a Seattle company must include such coverage in its employee health plan.

In a ruling issued June 12, **Judge Robert Lasnik** found that Seattle-based Bartell Drug Co.'s policy of excluding coverage for prescription contraception from an otherwise comprehensive employee health plan constitutes sex discrimination in violation of Title VII of the Civil Rights Act of 1964.[1]

EXECUTIVE SUMMARY

A federal judge has ruled that a Seattle-based company must pay for prescription contraceptives for its female employees in a decision that may lead employers around the country to do the same.

- The June 12 ruling found that Seattle-based Bartell Drug Co.'s policy of excluding coverage for prescription contraception from an otherwise comprehensive employee health plan constitutes sex discrimination in violation of Title VII of the Civil Rights Act of 1964.
- While binding only in western Washington, legal advocates believe the ruling will open the door to more companies including prescription contraceptive coverage in their health plans. Women who wish to pursue such coverage with their companies can access a web site, www.covermypills.org, or by dialing a toll-free number, (800) 727-2996, for more information.

The class action lawsuit was filed on behalf of **Jennifer Erickson**, RPh, who is the head pharmacist at one of the company's Bellevue stores.[2] ***(Contraceptive Technology Update* reported on the filing of the lawsuit in its March 2001 issue; see p. 25.)**

"Male and female employees have different, sex-based disability and health care needs, and the law is no longer blind to the fact that only women can get pregnant, bear children, or use prescription contraception," ruled Lasnik. "The special or increased health care needs associated with a woman's unique sex-based characteristics must be met to the same extent, and on the same terms, as other health care needs."[1]

First of its kind

The class-action suit against Bartell was the first of its kind filed in federal court, according to attorneys in the case.[3] They predict the ruling is likely to influence other courts, although it is binding only in western Washington.

"This historic lawsuit was filed on behalf of the women whose basic health care needs are not being covered by their employer," said **Roberta Riley**, lead counsel and staff attorney with Planned Parenthood of Western Washington. "We are thrilled that the court has reversed this unfair and discriminatory policy."

The lawsuit was supported by the Fair Access to Contraception Coalition, which includes Planned Parenthood of Western Washington, the New York City-based Planned Parenthood Federation of America, the Washington, DC-based National Women's Law Center, and the American Civil Liberties Union of Washington and the Northwest Women's Law Center, both based in Seattle. The coalition has set up a web site, www.covermypills.org, with information to guide women in seeking contraceptive coverage from their employers. Women who are facing resistance in obtaining such coverage are encouraged to contact the coalition, either through the web site or by dialing a toll-free number, (800) 727-2996.

"I'm pleased with the decision and hope it encourages other women to go to covermypills.org to learn how they can work with their employers to get prescriptive contraception coverage, " said Erickson.

Company planned coverage

According to Bartell Drug Co., which operates 50 stores in King, Pierce, and Snohomish counties, the company had planned to include prescription contraceptive coverage in its health plan prior to the filing of the lawsuit. The company, which employs about 1,600 workers, says it began coverage of such drugs for union employees in April 2001 and had planned to add similar coverage for nonunion employees, including Erickson.[4]

"It was never our intention to discriminate, and we had planned to offer contraceptive coverage well before this judgment," said **Jean Bartell Barber**, the company's chief financial officer and granddaughter of the founder.

Indeed the company had not shown any bad faith or intent to discriminate, ruled Lasnik.

"There is no evidence or indication that Bartell's coverage decisions were intended to hinder women in their ability to participate in the work force or to deprive them of equal treatment in employment or benefits," ruled Lasnik.[1] "The most reasonable explanation for the current state of affairs is that the exclusion of women-only benefits is merely an unquestioned holdover from a time when employment-related benefits were doled out less equitably than they are today."

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Federal legislation coming on microbicides

By **Cynthia Dailard**
Senior Public Policy Associate
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Washington, DC

Microbicides — gels, creams, or suppositories that kill or deactivate disease-causing microorganisms — have tremendous potential to prevent the transmission of sexually transmitted diseases (STDs), including HIV.

Despite the importance of new female-controlled technologies for the prevention of HIV and other STDs, particularly in developing countries, microbicide research and development has been underfinanced and extremely slow. Fearing that they will not recoup the large expense of bringing to market a new product designed, in part, to be sold at low cost worldwide, large pharmaceutical companies have shied away from the field. Instead, innovation in this area has depended almost exclusively on academics and small biotech companies that are short on capital and depend on federal support to bring products to market. **(See information on microbicide research in two issues of *Contraceptive Technology Update* : March 1999, p. 25, and April 1999, p. 40; the fight for research funding in the June 2000 issue, p. 69; and the latest research advances in the May 2001 issue of *STD Quarterly*, p. 1, inserted in *CTU*.)**

Rep. Constance Morella (R-MD) is leading the charge on Capitol Hill to make vaginal microbicides a reality for women in this country and around the world. Yet Morella and other women's health advocates fear that without enhanced government involvement in this area, the 60-some microbicidal products in development may never make it to market.

Focus on funds, efforts

At a time when microbicides hold enormous promise for improving the public health, federal investment in this area is insufficient to keep microbicides moving through the research and development pipeline and into the hands of women, says Morella. Less than 1% of the budget for AIDS-related research at the Bethesda, MD-based National Institutes of Health (NIH) is being spent on microbicide development, and less than half of that money supports product development.

Another problem is that microbicide research at the federal level is decentralized and lacks coordination, microbicide advocates charge. Such research occurs within NIH, the Atlanta-based Centers for Disease Control and Prevention (CDC), and the Washington, DC-based U.S. Agency for International Development (USAID). To add another layer of complexity, microbicide research at NIH is housed within several institutes, with no single line of administrative accountability and no specific funding coordination. This lack of coordination and planning has lead to inefficiencies and duplication of effort in a field where resources are scarce, say advocates.

Seeking a solution

At the insistence of Morella and her House colleague, Rep. Nancy Pelosi (D-CA), NIH this year established a "microbicide program" and issued a five-year plan charting the future of microbicide research and development at NIH.

Sens. Patrick Leahy (D-VT), Arlen Specter (R-PA), and Tom Harkin (D-IA) secured $15 million in a foreign aid funding bill for microbicide research at USAID. That amount is nearly a $13 million increase over previous years.

Still more needs to be done, Morella says. This summer, she plans to introduce the *Micro-bicide Development Act of 2001*. Recognizing that $75 million is needed in fiscal year 2002 and $100 million is needed annually after that to capitalize on recent gains in this field, Morella's legislation calls for a substantial increase in federal investment for microbicide research and development in order to significantly expand and intensify microbicide-focused activities at NIH and CDC.

The bill also would establish four Centers for Microbicide Research and Development across the nation that would be devoted to research and development. The legislation also would require the secretary of health to coordinate federal microbicide activity and to collaborate with other federal agencies conducting work in this area.

The natural engines that drive new drug development have failed in the case of microbicides, so the government must take action, stated Morella at an April congressional meeting on the subject.

"With sufficient investment, a microbicide could be available within five years, to the very great benefit of the women of the world, their partners, and their children," she noted. ■

CTUPDATES

News ■ Resources ■ Events

Check out international family planning web site

Stay up to date on international family planning issues through a new web site: http://familyplanet.org.

The web site provides an international forum for discussion of family planning availability in various countries and diverse cultures around the world. It is a project of the Planet Campaign, which is designed to raise awareness of international family planning in the minds of the American public and to make it a priority among issues facing the United States and the world.

The public education campaign is the work of several organizations, including the Atlanta-based CARE, the New York City-based Planned Parenthood Federation of America and the National Audubon Society, the Westport, CT-based Save the Children, and the Washington, DC-based Population Action International and Communications Consortium Media Center. It is sponsored by the David and Lucile Packard Foundation of Los Altos, CA, and the William and Flora Hewlett Foundation of Menlo Park, CA.

The site allows visitors to send a postcard, mail a page of familyplanet.org, or download a background photo from its wallpaper gallery. Visitors also may sign up for Planet eNews, an e-mail newsletter of current developments in international family planning, or check out the site's book club, which recommends new books and moderates on-line book discussions. ▼

Web site adds 'shopping cart'

The web site www.managingcontraception.com now offers a "shopping cart" feature that allows family planners to purchase publications from the Decatur, GA-based Bridging The Gap Foundation.

Publications available for sale on the web site include *A Pocket Guide to Managing Contraception*, *A Personal Guide to Managing Contraception*, *Una Guía de Bolsillo Para El Uso de Anticoncepción* (The *Pocket Guide* in Spanish), and *Contraceptive Technology*, as well as other materials.

More information on Bridging the Gap publications is available by contacting: Bridging the Gap, 3031 E. Ponce de Leon Ave., Decatur, GA 30030. Telephone: (404) 373-0530. Fax: (404) 373-0480. E-mail: mcweb@managingcontraception.com. ▼

Get free review copies of abstinence material

Journeyworks Publishing of Santa Cruz, CA, has released two new brochures on abstinence for use in helping teens make decisions on sexual activity.

Abstinence: Tough Questions, Good Answers addresses questions such as "Is it normal not to have sex?" "Can I be abstinent now if I have had sex before?" and "Can I get an STD or become pregnant if I'm abstinent?" The pamphlet approaches abstinence as a choice to stay healthy, keep options open, and acknowledge one's own potential.

A Teen's Guide to Abstinence looks at why young people are choosing abstinence. It supports the decision to be abstinent and provides tips that can help young people follow through on their decision.

Journeyworks Publishing carries a wide

selection of educational material on teen pregnancy prevention, male responsibility, HIV / AIDS prevention, and sexually transmitted diseases (STD) prevention. All materials are reviewed by health professionals, teens, and young adults. Several titles are available in multiple languages.

A free review copy of the abstinence pamphlets is available to health professionals and educators by contacting Journeyworks Publishing, P.O. Box 8466, Santa Cruz, CA 95061-8466. Telephone: (800) 775-1998, 8:30 a.m.-4:30 p.m. PST. Monday-Friday. Fax: (800) 775-5853. Use your organization's letterhead for brochure requests. Web: www.journeyworks.com. For information on bulk pricing, please call (800) 775-1998. Prices start at 50 pamphlets for $15. ■

Sign up now for fall conferences

Family planners can stay current on pertinent health topics while earning continuing education credits, with attendance at the following fall national conferences:

• **Reproductive Health 2001** — Sept. 12-15, 2001, Washington, DC. The conference is sponsored by the Washington, DC-based Association of Reproductive Health Professionals (ARHP). The 38th annual conference will cover topics such as sexually transmitted infections, abortion, contraception, and social issues. Preconference sessions on Sept. 12 will cover midlife and adolescent health issues. A training session will be held Sept. 13 on the levonorgestrel intrauterine system; participants are asked to sign up for the session upon registration at the conference.

For more information, contact: Association of Reproductive Health Professionals, 2401 Pennsylvania Ave. N.W., Suite 350, Washington, DC 20037. Telephone: (877) 444-ARHP [(877) 444-2747]. Fax: (202) 466-3826. E-mail: conferences@arhp.org. On-line registration can be completed at the organization's web site: www.arhp.org.

• **Women's Health Care in the New Millenium** — Oct. 10-13, Lake Buena Vista, FL. This is the fourth annual conference sponsored by the Washington, DC-based National Association of Nurse Practitioners in Women's Health (NPWH).

Sessions will include a skill-building workshop on intrauterine devices, as well as seminars on nonhormonal management of menopause, pharmacologic management of incontinence, and contraceptive advances.

For more information, contact Katrina Roux, National Association of Nurse Practitioners in Women's Health, 503 Capitol Court N.E., Suite 300, Washington, DC 20002. Telephone: (202) 543-9693, ext. 1. E-mail: npwhdc@aol.com. On-line registration can be completed at the organization's web site: www.npwh.org. ■

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

- Identify the active ingredients in the oral contraceptive Cyclessa. **(See "News flash: Add new 25-mcg Cyclessa to triphasic oral contraceptive options.")**
- Name the leading reasons women discontinue hormone replacement therapy. **(See "Research gives nod to lower-dose HRT.")**
- State the name of the contraceptive patch now under development in the United States. **(See "Contraceptive patch, ring: In U.S. by 2001?")**
- Provide the name of the drug that, when used during pregnancy and the neonatal period, reduces the rate of mother-to-child HIV transmission by approximately two-thirds. **(See "Women and the spread of HIV/AIDS: Recognizing the female face in U.S. epidemic.")**

5. What are the active ingredients in the oral contraceptive Cyclessa?
   A. ethinyl estradiol and levonorgestrel
   B. ethinyl estradiol and desogestrel
   C. ethinyl estradiol and norgestimate
   D. ethinyl estradiol and norethindrone acetate
6. What is the leading reason women discontinue hormone replacement therapy?
   A. nausea
   B. breast tenderness
   C. vaginal atrophy
   D. vaginal bleeding
7. What is the name of the contraceptive patch developed by R.W. Johnson Research Institute?
   A. Ortho Evra
   B. CombiPatch
   C. Esclim
   D. FemPatch
8. What is the name of the drug that, when used during pregnancy and the neonatal period, reduces the rate of mother-to-child HIV transmission by approximately two-thirds?
   A. stavudine
   B. ritonavir
   C. zidovudine
   D. nelfinavir

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Association of Reproductive Health Professionals

S·T·D QUARTERLY™

Women and the spread of HIV/AIDS: Recognizing the female face in U.S. epidemic

Women represent 30% of new HIV infections and 23% of new cases of AIDS

Are you talking to your female patients about HIV / AIDS? It's time that you start the dialogue. In the United States, women represent 30% of new HIV infections and comprise 23% of new cases of AIDS.[1,2] Women of color are especially impacted by the disease. In 1999, African-American females accounted for 63% of new AIDS cases in women; 18% were Hispanic.[2]

The clock is ticking. According to a national survey, just 32% of women polled say they have spoken with a health care provider about HIV / AIDS; 20% say they have discussed the risks of being infected with HIV.[3]

Clinicians need to have a high index of suspicion when it comes to women and HIV / AIDS, says **Jean Anderson**, MD, associate professor of gynecology and obstetrics in medicine at Baltimore-based Johns Hopkins University. Anderson is editor of the just-released *A Guide to the Clinical Care of Women with HIV*, published by the HIV / AIDS Bureau of the Rockville, MD-based Health Resources and Services Administration. The manual provides practical, experience-based advice and treatment guidelines for clinicians treating women with HIV. **(The publication is available free of charge in print and Internet form. See the resource listing on p. 3.)**

The reality of the disease has changed much faster than the medical community's perceptions, states Anderson. Many clinicians still believe that injection drug users comprise the majority of the female HIV-infected population; however, the majority of new cases are heterosexually transmitted. According to the Atlanta-based Centers for Disease Control and Prevention (CDC), 75% of annual new infections are due to heterosexual transmission, with 25% attributed to injection drug use.[4]

While women of all ages are affected by HIV / AIDS, the disease is most prevalent among women in their childbearing years, notes Anderson. In 1999, 18% of new AIDS cases reported in women were among those ages 20-29, with 68% among those ages 30-49.[5]

Women with HIV / AIDS face their own set of challenges, contends Anderson. Since they are

EXECUTIVE SUMMARY

Women represent 30% of new HIV infections in the United States and 23% of new cases of AIDS. In 1999, African-American females accounted for 63% of new AIDS cases in women; 18% were Hispanic.

- The majority of new cases in women are heterosexually transmitted. According to the Centers for Disease Control and Prevention, 75% of annual new infections are due to heterosexual transmission, with 25% attributed to injection drug use.
- The federal government has just published a free clinical guide to care and treatment of women with HIV. More women are now living with HIV/AIDS, so clinicians must be prepared to provide supportive care.

often diagnosed later and generally have poorer access to care and medications, women tend to have higher viral loads and lower CD4 counts, she notes. Women living with HIV / AIDS also must contend with vulnerability related to reproductive issues and domestic violence, says Anderson.

"Women with HIV suffer more from stigma and are more vulnerable in some ways than men to violence, to abandonment, and to neglect of their own care, because they are basically caretakers for others," she notes.

Check prevention models

For clinicians to help women in HIV prevention, they must tap into the "power of the provider," says **Ann O'Leary**, PhD, senior behavioral scientist in the Division of HIV / AIDS Prevention in the CDC's National Center for HIV, STD, and TB Prevention.

"I think health care providers have a great deal of credibility and a great deal of respect from people," says O'Leary, co-editor of two books on women and AIDS. "If the health care provider says something is important, people really take it to heart."

O'Leary just conducted a workshop on two effective prevention programs at the annual meeting of the Washington, DC-based National Family Planning and Reproductive Health Association. Both programs are primary prevention interventions that have been shown to be effective on a biological outcome: STD infection. By reducing or eliminating STDs such as syphilis, gonorrhea, chlamydia, and herpes, clinicians may aid in reducing new HIV infections, as the presence of these STDs has been found to enhance HIV acquisition and transmission.

A study of the first prevention model, Project RESPECT, shows that interactive, client-centered HIV / STD counseling resulted in an overall reduction in STD incidence of about 30% after six months and 20% after 12 months of follow-up.[6] The STD reduction occurred among men and women and was observed consistently at all five study sites, according to the analysis. **(*Contraceptive Technology Update* reported on the project on p. 3 of the *STD Quarterly* inserted in the May 2001 issue. See resource listing on p. 3 to download information on Project RESPECT.)**

The second prevention model, a one-on-one provider / patient intervention that can be done in 20 minutes, also is well-suited for the family planning clinic environment, says O'Leary, a co-author of its analysis. The evaluation is in press and should be published by the close of this year, she reports.

Strides made in HIV/AIDS

Antiretroviral therapy and early detection represent two important strides in HIV care for women, says Anderson.

When it comes to perinatal transmission, research shows that use of zidovudine during pregnancy and the neonatal period reduces the rate of mother-to-child HIV transmission by approximately two-thirds.[7,8] New cases of AIDS in newborns declined 67% between 1992 and 1997, due in large part to increased treatment with zidovudine.[9]

The adoption of "universal, routine testing with patient notification" for prenatal HIV testing by the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) and the Elk Grove Village, IL-based American Academy of Pediatrics also play an important role in early detection, says Anderson. The groups issued their opinions following the 1998 recommendation by the Bethesda-based Institute of Medicine. **(*CTU* reported on ACOG's provider awareness campaign in the August 2000 issue, p. 96.)**

The development of antiretroviral therapies, and the approach to their use known as HAART (highly active antiretroviral therapy), has made a significant impact on HIV care, notes Anderson. HAART uses a combination of drugs to hit the virus at different points in its life cycle, which helps to suppress viral replication down to very low levels.

Due to therapeutic advances in care and prevention of vertical transmission, more women who know they are HIV-infected are choosing to become pregnant, states Anderson. Clinicians should discuss birth control options with these women and recognize that some may opt for pregnancy. Anderson suggests that clinicians consult the newly published *A Guide to the Clinical Care of Women With HIV* for information on preconception care. **(See resource box, p. 3.)**

"Women need to be counseled and educated about all the issues before they become pregnant, so that those who don't want to get pregnant can be helped to use the most effective method, and

RESOURCES

To view or download the Adobe Acrobat format of the publication, *A Guide to the Clinical Care of Women With HIV,* published by the HIV/AIDS Bureau of the Health Resources and Services Administration, visit http://hab.hrsa.gov/womencare.htm. To order free copies of the guide, contact:

- **Womencare**, Parklawn Building, Room 11A-33, 5600 Fishers Lane, Rockville, MD 20857. Fax: (301) 443-0791 (Attention: Womencare). E-mail: womencare@hrsa.gov.

To download counseling protocols, quality assurance protocols, and further information about Project RESPECT, go to the following Centers for Disease Control and Prevention web page: http://www.cdc.gov/hiv/projects/respect/default.htm.

those who do want to become pregnant can be educated about HIV in pregnancy and what advances we've made in terms of transmission," she states.

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Nightclubs join effort to stem STD spread

San Francisco public health officials and local club owners have joined forces to promote testing for sexually transmitted diseases (STDs) by offering free admission or a free drink to those who get tested.

While it is early in the promotion period, project organizers believe the "free passes" are putting the San Francisco Department of Public Health's City Clinic on the radar screen of club patrons, says **Larry Hanbrook**, community health specialist in the community-based STD services unit of the Department's STD Prevention and Control Services.

Recent data indicate increases in sexual risk taking among men who have sex with men (MSM) in a growing number of cities in the United States, including San Francisco.[1] The rise in sexually transmitted diseases (STDs) in this population is of concern, since STDs enhance the risk of sexually transmitted HIV infection.[2]

A target population for the San Francisco project is young gay men who are now experiencing the club scene, says Hanbrook. These young men are not aware of the increase in STDs and the need to protect themselves in light of the risk for HIV, says Hanbrook.

"Even if people don't come into the clinic, at least it will put the clinic on the radar screen," says Hanbrook. "

Four popular clubs are participating in the promotion, which kicked off during April, observed

EXECUTIVE SUMMARY

Public health officials in San Francisco have joined with local club owners to promote testing for sexually transmitted diseases (STDs). Clubs offer a free entrance pass or drink to encourage patrons to seek STD testing.

- The promotion is part of the department's response to increases in sexual risk behaviors, STDs, and HIV in men who have sex with men after years of decreases.
- Officials are targeting STD infections because they increase susceptibility to HIV.

as STD Awareness Month in San Francisco, says Hanbrook. Three are offering free admission as an incentive; one club, which does not charge admission, is offering a free drink.

When patrons enter a participating club, they are presented a business card-sized foldover card. The front flap resembles a theater ticket, with the headline, "Free Pass." Underneath the headline, the card instructs patrons to take the pass to the City Clinic, get a checkup, have the card stamped, and return it for a free entry or a free drink.

The inside of the card carries the message that many STDs may have symptoms, but they are not always apparent. Each card is site-specific, stating that "[name of club] wants to support your sexual health." Directions to the clinic are included, as are its operating hours. Cost for the project was low — under $100 for card production, says Hanbrook. The clubs are underwriting the entry or drink incentives. Hanbrook says he approached the clubs with the idea for the pilot project, and the owners readily agreed to join with the health department.

Stemming the spread

Health departments across the nation have recognized the increases in sexual risk behaviors, STDs, and — in San Francisco — HIV in men who have sex with men, says **Jeffrey Klausner**, MD, MPH, director of the city's STD Prevention and Control Services and assistant professor of medicine at the University of California, San Francisco. These increases are of great concern because they come after years of reduced sexual risk behaviors and dramatic declines in STD and HIV incidence in the MSM population, he says.

According to Klausner, many factors play into the increases: decreased concern about the seriousness of HIV infection and AIDS related to recent advances in HIV treatment; persons with HIV living longer and healthier lives and having restored interest and participation in sex; a decreased community focus on HIV prevention; misperceptions about the transmissibility of HIV while persons are on HIV therapy; the continued influx of sexually active gay men into urban centers where the community memory of AIDS devastation has waned; and possibly, safe sex exhaustion among gay men without exposure to effective safer sex maintenance interventions.

Regardless of what is driving the increases in STDs, health departments must respond, contends Klausner. The San Francisco health department is participating in the media campaign, "HIV Stops With Me," which encourages persons with HIV to take responsibility. The San Francisco campaign combines multiple strategies, such as mass media, support groups, social events, community forums, provider training, and outreach, to help HIV-positive gay and bisexual men gain and use the skills necessary to prevent new HIV transmissions. (Check out components of the San Francisco campaign at www.hivstopswithme.org.)

Guidance for STD Clinical Preventive Services for Persons Infected with HIV, a new publication from the California STD Controllers Association and the Sacramento-based California Conference of Local AIDS Directors, recommends routine sexual health assessments and screening in persons infected with HIV, states Klausner. The document can be downloaded free of charge as an Adobe Acrobat PDF file at www.dph.sf.ca.us/sfcity clinic/info/bulletin%204_18.pdf.

"The key message that every patient needs to understand is that the sign of a good provider is one who asks about sexual health and screens for STDs, when appropriate," says Klausner. "Professional organizations and public health agencies have advocated for sexual health to become an important part of every clinical examination, but not until patients expect this from providers will providers practice behavior change."

SOURCE

For more information on the San Francisco program, contact:

- **Larry Hanbrook**, Community-Based STD Services Unit, STD Prevention and Control Services, San Francisco Department of Public Health, 1360 Mission St., Suite 401, San Francisco, CA 94103. E-mail: larry_hanbrook@dph.sf.ca.us.

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Hormone Replacement Therapy
General Information

What is it? Hormone replacement therapy (HRT) is a treatment for women who have low hormone levels, like a woman going through menopause. HRT also is called estrogen (es-tro-jin) replacement therapy or ERT. With HRT a woman takes estrogen, and often progestin (pro-jes-tin), to help the symptoms caused by low hormone levels in her body.

What are hormones and how do they work?

- Hormones are special chemicals that your body makes. The job of hormones is to control how different parts of your body work. The main female hormones are estrogen and progesterone (pro-jes-ter-own) which are made by your ovaries. These hormones are a very important part of your reproductive system.
- Estrogen is made during your menstrual cycle. Its job is to grow a thick layer of tissue inside the uterus (womb) each month. Estrogen also affects your bones and the health of your heart and blood vessels. Progesterone is made by your ovaries during the second half of your menstrual cycle. It further thickens the lining of the uterus. During menopause, usually in the late 40s or early 50s, your ovaries slowly stop making these hormones.

What are the reasons I may not have enough estrogen?

- **Menopause.** The most common reason for having low estrogen is menopause. Another name for menopause is “change of life” or “the change.” This is a time in a woman’s life when menstrual or monthly periods slow down and with time, completely stop. Menopause usually begins at ages 45-50. The average age when a woman’s monthly period stops is 51 years. But a woman can go through menopause much younger.

- **Removal of ovaries.** Estrogen levels will drop if a woman has both ovaries removed. Menopause symptoms start right away when the ovaries are removed because there is no more estrogen.

- **Other reasons.** Too much exercise may cause your estrogen level to drop, which can stop your monthly periods. Your estrogen level may also drop if you lose large amounts of weight.

- **What are the signs and symptoms of a low estrogen level?** You can have physical and emotional changes when your estrogen level is low.

- **Hot flashes.** This is the most common symptom of menopause. A hot flash is a sudden feeling of heat that spreads throughout your body. Your skin may also sweat or blush. Hot flashes usually happen at night and may wake you up. You may have hot flashes on and off for many years.

- **Osteoporosis (ah-stee-o-per-o-sis).** This is also called bone loss. After menopause a woman’s bones begin losing calcium and protein. This may cause brittle bones, which can make older women more likely to break bones.

- **Heart and blood vessel disease.** Heart disease is the leading cause of death of women in the United States. Estrogen seems to help prevent heart disease. You are more likely to have heart and blood vessel disease after menopause.

- **Emotional changes.** Low estrogen levels may cause emotional changes. These emotional changes may be linked to physical changes, like losing sleep because of hot flashes. Some women feel nervous, depressed, tired, or short-tempered. You also may have concentration problems (staying focused).

- **Vaginal dryness.** The lining of the vagina may get thinner and less elastic because of dropping estrogen levels. A decrease in estrogen may cause your vagina to become dry. These changes may cause you to have pain during sex.

Will HRT help these symptoms? You may choose to take HRT to help or prevent the symptoms of low estrogen. Hot flashes and night sweats will occur less often and may possibly go away if you take estrogen. Estrogen helps prevent vaginal dryness and thinning of the tissue inside the vagina. Your chances of breaking a bone are much lower if you take estrogen. HRT may also improve your mood and memory. HRT may reduce your risk of heart disease.

Is HRT safe?

- HRT is not right for everyone. There is some concern that taking estrogen may cause cancer of the endometrium (end-o-mee-tree-um). The endometrium is the lining of your uterus. You do not need to worry about this if you have had your uterus removed during surgery. Taking progestin with estrogen may decrease the risk of getting this kind of cancer. Progestin is a man-made kind of progesterone. It is not known if progestin blocks any of the benefits that estrogen adds to prevent heart disease.

- Any vaginal bleeding should be carefully watched if you choose not to take progestin. You may have vaginal bleeding once a month if you take progestin with estrogen.

- There does seem to be a link between HRT and breast cancer. You should do a breast self-exam every month. You and your caregiver can decide when you should have a mammogram. Your caregiver may suggest you have a mammogram if your mother or sister had breast cancer.

- Your caregiver will help you decide if you can safely take HRT. Tell your caregiver if you have any of the following.
  - —Blood clotting problems.
  - —Breast cancer.
  - —Cancer in the lining of your uterus.
  - —Liver disease.
  - —Think you may be pregnant.
  - —Vaginal bleeding problems.

Are there side effects with HRT? Following are possible side effects of HRT.
- Abdominal (belly) cramping.
- Headaches.
- Mood changes.
- Nausea (upset stomach).
- Possible breast cancer.
- Possible endometrial cancer.
- Possible weight gain.
- Swelling of abdomen, hands, or feet.
- Swollen breasts and breast tenderness.
- Uterine bleeding.

How long do I need to take HRT? Bone loss is highest during the early years after menopause. To get the best results, HRT should start soon after the beginning of menopause. You should continue with HRT for at least seven to 10 years. You and your caregiver can decide how long you should take HRT. You will need long-term treatment if you are trying to prevent heart disease or osteoporosis. Bone loss will begin right away when you stop taking HRT.

How do I take HRT?

- There are different ways to take HRT. The most common way to take HRT is as a pill. But estrogen may be given as a skin patch or as a cream or ointment to be put into your vagina. An implant is another way to take estrogen. A pellet that contains pure estrogen is put beneath the skin and fatty layer of your abdomen or buttock. The pellet releases estrogen for four to eight months.

- Many women take estrogen and progestin. The amount of each hormone needed to reduce or prevent menopause symptoms is different from woman to woman. Your caregiver may need to change the amount of estrogen or progestin that you take.

- You may only need to take estrogen if you have had a hysterectomy (hiss-ter-ek-tuh-mee). This is because there is no risk of getting endometrial cancer since your uterus has been removed.

Are there other ways to prevent bone loss or heart disease without HRT? Eating foods that are rich in calcium and low in fat is one way to control bone loss and heart disease. Caregivers may give you medicine to prevent bone loss or heart disease. Other ways to prevent bone loss and heart disease are to exercise regularly and to limit the amount of alcohol that you drink. You should not have more than one drink a day. A drink is 1½ ounces of whiskey, 5 ounces of wine, or 12 ounces of beer (regular or light). If you smoke, you should quit.

How often should I see my caregiver if I take HRT? Call your caregiver if you are bleeding from your vagina or have other side effects that are bothering you. You should see your caregiver every year for a checkup. Your caregiver may want you to have the following tests.

- **Pap smear.** This is a test to check for cancer of the cervix. The cervix is the bottom part of your uterus. You should have a Pap smear every year.

- **Blood pressure check.** Your blood pressure should be checked every year.

- **Mammogram.** This is an X-ray of the breasts. Tell your caregiver if you have had a mammogram that is not normal. The American Cancer Society suggests women age 40 or older have a mammogram every year.

- **Endometrial biopsy.** This is when a small piece of tissue is removed from the lining of the uterus. It is then sent to the lab to be tested for cancer. You should have an endometrial biopsy every year if you are only taking estrogen.

- **Blood cholesterol levels.** Estrogen helps keep a higher level of HDL cholesterol. This is the “good” cholesterol that protects against heart disease. Estrogen decreases the LDL level, which is the “bad” kind of cholesterol. As your body makes less estrogen during menopause, the HDL level goes down while the LDL goes up.

Where can I get more information about HRT? You can call or write the following organizations for more information:

- American Heart Association, 7272 Greenville Ave., Dallas, TX 75231-4596. Telephone: (800) 242-8721.
- National Cancer Institute. Web: www.oncolink.upenn.edu/pdq_html/6/engl/600310.html.
- National Heart, Lung, and Blood Institute, P.O. Box 30105, Bethesda, MD 20824-0105. Telephone: (301) 592-8573.
- National Osteoporosis Foundation, 1150 17th St. N.W., No. 500, Washington, DC 20036. Telephone: (800) 223-9994.
- Office of Research on Women’s Health, National Institutes of Health, Building 1, Room 201, Bethesda, MD 20892-0161. Telephone: (301) 402-1770.
- The American College of Obstetricians and Gynecologists, 409 12th St. S.W., Washington, DC 20024-2188. Telephone: (202) 638-5577.

CARE AGREEMENT:

You have the right to help plan your care. To help with this plan you must learn about hormone replacement therapy. You can then discuss the treatment options with caregivers. Work with them to decide what care will be used to treat your decreasing estrogen levels. You always have the right to refuse treatment.

Source: Klasco R, Auracher P (Eds). CareNotes™ System. MICROMEDEX Inc., Englewood, CO (Edition expires 9/2001).

Terapia de Reemplazo Hormonal
Información General

¿Qué es? La terapia de reemplazo hormonal (TRH) es un tratamiento para las mujeres que tienen bajos niveles hormonales, como una mujer que está pasando por la menopausia. Esta terapia también es conocida también como terapia de reemplazo estrogénico o TRE. Durante esta terapia, la mujer toma estrógeno o progestina para mejorar los síntomas causados por los bajos niveles de hormonas en su cuerpo.

¿Qué son las hormonas y cual es su función?

- Las hormonas son unos químicos especiales producidos por su cuerpo. La función de las hormonas, es controlar el funcionamiento de las diferentes partes de su cuerpo. Las principales hormonas femeninas son el estrógeno y la progesterona, las cuales, se producen en sus ovarios. Estas hormonas, son una parte muy importante de su sistema reproductor.
- El estrógeno se produce durante la menstruación. Su función es desarrollar mensualmente, una gruesa capa de tejido dentro del útero (matriz). El estrógeno también afecta sus huesos y la salud de su corazón y vasos sanguíneos. La progesterona es producida en sus ovarios en la segunda parte del ciclo menstrual. Esta hormona engruesa un poco más el revestimiento del útero. Durante la menopausia, entre las edades al final de los 40 años y al principio de los 50, sus ovarios dejan lentamente, de producir estas hormonas.

¿Cuáles son las razones que me impiden tener suficiente estrógeno?

- **Menopausia:** La razón más común para tener el estrógeno bajo, es la menopausia. Otro nombre para la menopausia es 'cambio de vida' o simplemente 'el cambio'. Esta, es una época en la vida de la mujer, en la cual, la menstruación disminuye y con el tiempo desaparece por completo. Generalmente, la menopausia comienza entre los 45 y los 50 años de edad. El promedio de edad cuando la menstruación desaparece por completo, son los 51 años. Pero una mujer puede pasar por la menopausia, a una edad más joven.
- **Extirpación de los ovarios:** Los niveles de estrógeno descenderán si los ovarios de una mujer son extirpados. Cuando los ovarios son extirpados, los síntomas de la menopausia comienzan inmediatamente, porque desaparece la producción de estrógeno.
- **Otras razones:** El exceso de ejercicio hace que los niveles de estrógeno disminuyan deteniendo así, los periodos mensuales. Si usted pierde demasiado peso, los niveles de estrógeno también caerán.

¿Cuáles son los signos y síntomas que indican la disminución en el nivel de estrógeno? Cuando el nivel del estrógeno es demasiado bajo, se presentan algunos cambios físicos y emocionales.

- **Calores.** Las oleadas de calor son el síntoma más común de la menopausia. Estas oleadas son brotes de calor súbitos que se extienden por todo el cuerpo. Su piel, también, puede sudar o sonrojarse. Usualmente, estos calores se presentan durante la noche y pueden despertarla. Usted puede presentar oleadas de calor que aparecen y desaparecen durante varios años.
- **Osteoporosis.** Esta también es llamada pérdida ósea. Después de la menopausia, los huesos de la mujer comienzan a perder calcio y proteína. Esta pérdida hace que sus huesos se vuelvan quebradizos y por esta razón, las mujeres de edad avanzada son más propensas a sufrir fracturas en los huesos.
- **Enfermedad del corazón y de los vasos sanguíneos.** La enfermedad del corazón es la causa predominante de la muerte de las mujeres en los Estados Unidos. Parece, que el estrógeno ayuda a prevenir la enfermedad del corazón. Usted es más propensa a sufrir del corazón y de los vasos sanguíneos, después de la menopausia.
- **Cambios emocionales.** El bajo nivel de estrógeno causa cambios emocionales. Estos cambios emocionales pueden estar relacionados con los cambios físicos, como el insomnio, que se presenta debido a los calores súbitos. Algunas mujeres se sienten deprimidas, nerviosas, cansadas o indispuestas. También, pueden tener problemas de concentración (desenfocadas).

- **Resecamiento vaginal.** El revestimiento de la vagina puede adelgazarse y ser menos elástico, debido a la caída de los niveles de estrógeno. Una disminución en el estrógeno puede ser la causa de la resecamiento en su vagina. Estos cambios hacen que sus relaciones sexuales sean dolorosas.

¿Ayudará la TRH a mejorar estos síntomas? Usted puede someterse a la TRH para mejorar o prevenir los síntomas producidos por la caída del nivel de estrógeno. Si usted toma estrógeno, los calores y sudores nocturnos ocurrirán con menos frecuencia y pueden desaparecer. El estrógeno ayuda a prevenir el resecamiento vaginal, y el adelgazamiento del tejido en el interior de la vagina. Las probabilidades de romperse un hueso son mucho menores si, usted, usa estrógeno. La TRH, también puede mejorar su mal genio, su memoria y reducir su riesgo de enfermedad al corazón.

¿Es segura la TRH?
- La TRH no es favorable para todas las mujeres. Existe la inquietud que, tomar estrógeno, produce cáncer en el endometrio. El endometrio es el revestimiento de su útero. Usted no tiene que preocuparse por esto si, su útero, ha sido extirpado durante la cirugía. Tomar progestina con el estrógeno, puede disminuir el riesgo de contraer esta clase de cáncer. La progestina es una clase de progesterona sintética (fabricada por el hombre). No se sabe si, la progestina, neutraliza alguno de los beneficios que, el estrógeno ofrece, para prevenir la enfermedad cardíaca.
- Cualquier sangrado vaginal que se presente, debe vigilarse cuidadosamente si usted decide no tomar la progestina. Si toma progestina con estrógeno, usted puede tener sangrado vaginal, una vez al mes.
- Parece que, si existe relación entre la TRH y el cáncer de seno. Usted debe hacerse la auto palpación de los senos mensualmente. Usted y su médico decidirán la fecha en que usted debe hacerse una mamografía. Si su madre o su hermana, han tenido cáncer de seno, es posible que su médico, le ordene una mamografía.
- Su médico la ayudará a decidir si usted, puede someterse a la TRH sin correr ningún riesgo. Si usted presenta alguna de las siguientes anomalías, infórmele a su médico.
- Problemas de coagulación de la sangre.
- Cáncer de seno Cáncer en el revestimiento de su útero. Enfermedad del hígado. Piensa que está embarazada. Problemas de sangrado vaginal.

¿Se presentan efectos secundarios debido a la TRH? A continuación, mencionaremos los posibles efectos secundarios.
- Calambres abdominales. Dolores de cabeza. Cambios de genio. Náuseas. Posible cáncer de seno. Posible cáncer en el revestimiento de su útero. Posible subida de peso. Inflamación en el abdomen, manos o pies. Senos hinchados y sensibles. Sangrado uterino.

¿Cuánto tiempo necesito para hacerme la TRH? La pérdida ósea es mayor, durante los primeros años después de la menopausia. Para conseguir los mejores resultados, la TRH debe comenzarse al poco tiempo de haber comenzado la menopausia. Usted debe continuar con la TRH al menos durante 7 a 10 años. Usted y su médico, decidirán por cuanto tiempo debería hacerse la TRH. Usted necesitará un tratamiento a largo plazo si, está tratando de prevenir la enfermedad cardíaca o la osteoporosis. La pérdida ósea, comenzará inmediatamente después de haber suspendido la TRH.

¿Cómo me someto a la TRH?
- Hay diferentes formas de hacerse la TRH. La más común es hacerse la TRH mediante el consumo de píldoras. El estrógeno puede administrarse mediante un parche en la piel o en forma de crema o de ungüento, que se aplica en su vagina. Otra forma de administrar el estrógeno, es mediante un implante. Se coloca una píldora que contiene estrógeno puro debajo de la piel y de la capa de grasa de su abdomen o sus glúteos (nalgas). La píldora permanece liberando estrógeno, por 4 a 8 meses.
- Muchas mujeres toman estrógeno y progestina. La cantidad de cada hormona que se necesita para reducir o prevenir los síntomas de la menopausia, es diferente para cada mujer. Puede ser necesario que su médico cambie la cantidad de estrógeno o de progestina que usted toma.

- Es posible que necesite tomar estrógeno solamente si le han hecho a una histerectomía. La razón es, que no existe riesgo de contraer cáncer endometrial puesto que su útero, ha sido extirpado.

¿Existen otras formas de prevenir la pérdida ósea o la enfermedad cardíaca sin someterse a la TRH? El consumo de alimentos ricos en calcio y bajos en grasa es una forma de controlar la pérdida ósea o la enfermedad cardíaca. Los médicos pueden ordenarle medicinas para prevenir pérdida ósea o enfermedad cardíaca. Otra forma de prevenir estos dos problemas, es ejercitarse regularmente y limitar el consumo de alcohol. Usted no debe tomarse más de 1 trago al día. Un trago equivale a 1½ onza de whiskey, a 5 onzas de vino o, a 12 onzas de cerveza (suave o regular). Si usted fuma, debería dejar de hacerlo.

¿Qué tan frecuentemente debo visitar a mi médico si me someto a la TRH? Si tiene sangrado vaginal o presenta otros efectos secundarios que le causen molestias, llame a su médico. Usted debe visitar a su médico todos los años, para que le haga un chequeo. Su médico puede ordenarle los siguientes exámenes.

- **Citología.** Este examen, también es conocido como Papanicolau o Pap y sirve para detectar el cáncer de la cérvix. La cérvix es la parte inferior de su útero. Usted debe hacerse este examen todos los años.
- **Chequeo de la presión arterial.** La presión arterial debe chequearse todos los años.
- **Mamografía.** La mamografía es una radiografía de sus senos. Si usted ha tenido una mamografía anormal, infórmele a su médico. La Sociedad Americana de Cancerología sugiere que las mujeres mayores de 40 años se hagan una mamografía todos los años.
- **Biopsia endometrial.** Esta biopsia consiste en extraer un pequeño pedazo del tejido que reviste al útero. Luego, esta muestra es enviada al laboratorio para que la examinen y determinen si, hay presencia de cáncer. Si está tomando estrógeno solamente, usted debe hacerse una biopsia endometrial todos los años.
- **Niveles de colesterol en la sangre.** El estrógeno ayuda a mantener más altos los niveles de colesterol HDL. Este, es el colesterol "bueno" porque la protege de las enfermedades cardíacas. El estrógeno disminuye los niveles de colesterol LDL, el cual, es el colesterol "malo". A medida que su cuerpo produce menos estrógeno durante la menopausia, el nivel del colesterol HDL decrece, mientras que los niveles del colesterol LDL aumentan.

¿Dónde puedo conseguir más información relacionada con la TRH? Para mayor información, escriba o llame a las siguientes organizaciones.

- American Heart Association, 7272 Greenville Ave., Dallas, TX 75231-4596. Teléfono: (800) 242-8721.
- National Cancer Institute. www.oncolink.upenn.edu/pdq_html/6/engl/600310.html.
- National Heart, Lung, and Blood Institute, P.O. Box 30105, Bethesda, MD 20824-0105. Teléfono: (301) 592-8573.
- National Osteoporosis Foundation, 1150 17th St. N.W., No. 500, Washington, DC 20036. Teléfono: (800) 223-9994.
- Office of Research on Women's Health, National Institutes of Health, Building 1, Room 201, Bethesda, MD 20892-0161. Teléfono: (301) 402-1770.
- The American College of Obstetricians and Gynecologists, 409 12th St. S.W., Washington, DC 20024-2188. Teléfono: (202) 638-5577.

ACUERDOS SOBRE SU CUIDADO: Usted tiene el derecho de participar en el plan de su cuidado. Para participar en este plan, usted debe aprender acerca de la terapia de reemplazo hormonal. De esta forma, usted y sus médicos pueden hablar acerca de sus opciones y decidir que tratamiento se usará para su cuidado. Usted siempre tiene el derecho a rechazar su tratamiento.

Source: Klasco R, Auracher P (Eds). CareNotes™ System. MICROMEDEX Inc., Englewood, CO (Edition expires 9/2001).