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INSIDE

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Include pharmacists in the loop when it comes to ECP education

Only 3 of 100 NYC pharmacists gave correct info before Preven launch

Whether you are writing prescriptions for Preven or for single packs of the 11 other combined oral contraceptives declared safe and effective as emergency contraceptive pills (ECPs), remember that education plays a large role in the process. This education needs to be extended not only to patients, but to the pharmacists who fill the prescriptions outside clinic facility walls.

Less than a year after the U.S. Food and Drug Administration approved the Preven Emergency Contraceptive Kit as the first product specifically marketed for emergency contraception, pharmaceutical distribution has exceeded company projections. Preven has 65% to 70% all-commodities distribution, according to **Roderick Mackenzie**, chairman of Gynétics of Belle Mead, NJ, marketer of the Preven kit. "What that means is that Preven can be purchased by women in most of their local drug stores," says Mackenzie. "All-commodities distribution pharmacies fill between 65 [and] 70% of all prescriptions filled in the U.S."

Preven sales have soared at family planning clinics, inner-city medical facilities, and college health centers, with 1.3 million sold in the first three months they were available in 1998.[1]

EXECUTIVE SUMMARY

Preven, the first dedicated emergency contraceptive pill (ECP), is gaining its place in the market. Education is being offered to pharmacists who dispense medications to patients outside clinic facilities.

- Before Preven's debut, an ECP survey of 100 New York City pharmacists revealed that only three could supply correct information on three key points. Pharmacist notification and education was included in the Preven launch, says Gynétics, Preven's marketer.
- Working with the state pharmacists' association, the Program for Appropriate Technology of Seattle has launched a pilot project allowing pharmacists to dispense ECPs directly to women. More than 800 Washington pharmacists have received training.

Before the September 1998 debut of Preven, Planned Parenthood of New York City conducted a telephone interview of 100 metro pharmacists to assess their knowledge of emergency contraception. They were graded on whether they stated three key points:

- High doses of normal birth control pills are the most common method of emergency contraception.
- ECPs can be taken up to 72 hours after unprotected sex.
- ECPs are available only through prescription.

Rating of the responses showed 37 as poor, meaning the pharmacists gave no or only incorrect information; 24 as fair; 28 as good; and eight as very good. Only three responses were graded as excellent, whereby the pharmacist correctly informed the caller of all three key facts about emergency contraception.

"The survey sprung directly from questions and comments coming from our patients who had been receiving either no information or misinformation from their local pharmacists," says **Alexander Sanger**, president of the New York Planned Parenthood affiliate. "We were worried about women stopping at the pharmacist with this misinformation and waiting to see whether or not they got pregnant."

Druggists' learning curve

Family planners are quite familiar with the timetable that has evolved since the FDA affirmed the safety and efficacy of the use of certain oral contraceptives in emergency contraception in a Feb. 25, 1997, notice in the *Federal Register.* However, pharmacists may not have been as aware of the steps leading to the launch of the first dedicated ECP product, according to **Susan Winckler**, RPh, director of policy and legislation for the American Pharmaceutical Association in Washington, DC. The association is the largest U.S. pharmacist organization, representing more than 53,000 pharmacists.

When the FDA published its 1997 *Federal Register* notice, it was not accompanied by publicity from the companies who manufacture the pills listed in the notice, says Winckler. When the Preven kit made its debut in 1998, the term "emergency contraception" may not have been in pharmacists' everyday language, she surmises.

Education has been an important part of Preven's product launch, according to Gynétics. Before the market introduction of the drug, every pharmacy in the United States received notification of the FDA approval, a description of the contents of the Preven Kit, and an explanation that Preven works the same way birth control does, says Mackenzie. In addition, the company provided an overview of the marketing effort, ordering information, and access to Gynétics' toll-free hotline and Web site. News of the availability of Preven was covered by every major pharmacy journal.

Planned Parenthood of New York City plans to partner with pharmacist professional trade associations and local schools of pharmacy to offer educational and promotional opportunities on emergency contraception. It also is following up with the pharmacies included in its survey to make sure pharmacists have correct emergency contraception information in hand.

Sanger also sees direct consumer advertising as an important way to raise awareness of emergency contraception. The New York affiliate has run two sets of subway advertisements that resulted in a 62% increase in emergency contraception appointments at Planned Parenthood clinics. (Planned Parenthood of Georgia also is using advertising to promote its Emergency Contraception Connection, a statewide toll-free hotline that provides over-the-phone medical assessments and ECP prescriptions to qualified candidates. **For details, see story, p. 64.**)

Three of the ads — two versions in English and one in Spanish — ran for six weeks in New York City subways. The ads are simply designed, with rumpled sheets in the background and descriptive "pillow talk" spelled out on the foreground. They read: "Oooh . . . oooh . . . oops!" and "Ohhh . . . ohhh . . . uh-oh!" The text also includes this fact: "Emergency contraception can prevent pregnancy

COMING IN FUTURE MONTHS

- Anti-nausea drugs and ECPs: New data
- Interviewing teens: Tricks of the trade
- Teen centers in pharmacies
- Contraceptive use in Hispanic women
- Screen, treat, prevent to stop STD spread

up to three days after sex," the logo, and a toll-free number. National Planned Parenthood Federation of America organization in New York City has adopted the campaign.

By educating pharmacists and patients on emergency contraception, there will be fewer barriers to access, which can only bode well for women, says Sanger.

Washington a success

Getting information directly into pharmacists' hands has been an important element in the success of expanding ECP access through a novel Washington state project. The pilot project is a collaboration among the Program for Appropriate Technology (PATH), the Washington State Pharmacists Association, the University of Washington Department of Pharmacy, the Washington State Board of Pharmacy, and Elgin DDB Needham advertising agency, all in Seattle. **(See *Contraceptive Technology Update*, June 1998, p. 79, for an overview of the project.)**

PATH has just completed a workshop to help other states replicate the project, which allows pharmacists to dispense ECPs directly through a collaborative agreement with a provider with prescriptive authority. The joint agreement allows the pharmacist to screen, counsel, and prescribe ECPs to women under a standard protocol agreement.

The Washington State Pharmacists Association has conducted a three-hour continuing education training for pharmacists in the state, with more than 800 pharmacists trained since the project began, says **Jane Hutchings**, MPH, senior program officer at PATH. ECP training, based on the training offered through the project, has been incorporated into the curricula of the two state pharmacy schools at the University of Washington in Seattle and Washington State University in Pullman.

The pharmacist training has emphasized several critical points, including these:

- ECPs are regular birth control pills. Their mechanism of action is the same as regular daily cyclical birth control pills, and pharmacists have been filling prescriptions for birth control pills for years.
- ECPs do not dislodge or have an adverse effect on an established pregnancy and therefore are very different than RU-486 (mifepristone).

All training participants receive a notebook covering therapeutic and dispensing information, patient care issues, collaborative agreements, public relations, referral resources for ongoing contraception, and other reproductive health issues. The notebooks also include reprints of the *Federal Register* notice and the practice pattern on emergency contraception from the American College of Obstetricians and Gynecologists in Washington, DC, both of which address the safety of ECPs and the approved use of oral contraceptives for ECP use. **(See resource listing, below, for more on the pharmacists' project, as well as information on providing ECPs.)**

While the project's grant only targeted three large training sessions, organizers quickly found that smaller "quick response" talks made the difference, says **Don Downing**, RPh, pharmaceutical care provider with the University of Washington, Washington State University, and the Washington State Pharmacists Association.

These "guerrilla sessions" were set up after interest was identified within a group of pharmacists in a given part of the state, with organizers going directly to hospitals, staff rooms, and other locations to provide training to smaller numbers of enthusiastic practitioners. Interested doctors and nurses were invited to the training free of charge, and these invitations resulted in raised awareness of how pharmacists could lower barriers to access.

"Pharmacists here received information on ECPs from multiple channels," Hutchings says. "In addition to answering basic questions about

RESOURCES

For more on the Washington state pilot project to increase access to emergency contraception, contact:

- **Jane Hutchings**, MPH, Program for Appropriate Technology in Health, 4 Nickerson St., Seattle, WA 98109. Telephone: (206) 285-3500. Fax: (206) 285-6619. E-mail: jh@path.org.

To order provider and patient materials on emergency contraception, contact:

- **Marketing Department**, Planned Parenthood Federation of America, 810 Seventh Ave., New York, NY 10019. Telephone: (800) 669-0156, 9 a.m.-5 p.m. EST. Fax: (212) 261-4362. Item No. 5410, "Emergency Contraception: Resources for Providers," contains key information on providing ECPs. Each packet is $5, with 15% shipping and handling; sales tax charged only in California, District of Columbia, Florida, Georgia, and Illinois. Visit the Program for Applied Technology Web site at http://www.path.org/acog to print out an Adobe Acrobat PDF order form, which also allows providers to order other pertinent EC items.

ECPs and dispelling misinformation, this outreach also provided information on unintended pregnancy and the public health need for ECPs."

Reference

1. Henry J. Kaiser Family Foundation. Emergency contraception: Sales figures show widespread use as demand increases. *Kaiser Daily Reproductive Health Report.* Menlo Park, CA; March 3, 1999. ■

One call does it all for women seeking ECPs

The condom broke. The diaphragm remained on the bedside table. No protection was available, and intercourse occurred. For women in Georgia, each of those situations now can be remedied with a toll-free call to the Emergency Contraception Connection operated by Planned Parenthood of Georgia in Atlanta.

No matter where women are located in the state, they can receive a confidential medical assessment over the telephone. If the assessment indicates candidacy for emergency contraceptive pills (ECPs), a prescription is called in to a convenient local pharmacy.

"I think that all of us are concerned about reducing the need for abortion," says **Kay Scott**, president and chief executive officer of the Georgia organization. "One of things that we wanted to do was to make sure that emergency contraception was out there for the people most in need."

EXECUTIVE SUMMARY

Planned Parenthood of Georgia has expanded access to emergency contraceptive pills (ECPs) through a toll-free hotline.

- Women can call six days a week and speak with a Planned Parenthood counselor, who asks questions to determine ECP candidacy. Responses are reviewed by a nurse practitioner, and if the caller is determined to be a candidate, the provider calls in a prescription per medical protocol to a drug store.
- Planned Parenthood of Georgia is using radio, newspaper, and billboard ads, as well as a Web site, to promote its program. A 30% increase in ECP use has been noted since the program's February inception.

A survey of local Planned Parenthood clients revealed large gaps in knowledge about emergency contraception. Most of the women either knew nothing of the method or incorrectly believed it was a form of abortion, says Scott.

Even providers affiliated with the organization's medical board and local health maintenance organizations weren't clued in on all the facts about emergency contraception or the need for easy access. Planned Parenthood of Georgia set out to expand knowledge of ECPs through an extensive marketing campaign and the development of the Emergency Contraception Connection hotline.

Through a start-up grant from an anonymous private foundation, the organization developed a series of billboard, radio, and newspaper ads about the availability of emergency contraception, as well as designed a Web site. Pocket cards and posters were developed for use in each of the five state Planned Parenthood facilities. The pocket cards, which mirror the newspaper ads, show an illustration of a bed with the caption, "More accidents happen here than in the kitchen." The card then gives a short explanation of emergency contraception, its availability through the Connection hotline and Planned Parenthood clinics, and telephone numbers.

Making the assessment

The highlight of the program is the Emergency Contraception Connection hotline. The hotline was activated in February and, in its short period of operation, has resulted in a 30% increase in ECP use, says Scott. The hotline is staffed from 9 a.m. to 5 p.m. by a full-time counselor, who does the initial telephone assessment, and a nurse practitioner, who reviews the assessments for candidacy and calls in the prescriptions under medical protocol.

The hotline was envisioned as a seven-day-a-week venture. In monitoring usage patterns, however, the lack of calls on Sunday led to removing that day of service. Most calls occur on Monday, Thursday, Friday, and Saturday, with Monday showing the highest volume of use, she says.

Planned Parenthood of Georgia developed a proprietary computer program to prompt the counselor through the required steps in gathering the needed medical history and informed consents needed for potential ECP candidacy. Depending on the number of questions the patient asks, an average call takes about 20 minutes, says **Lisa Ferguson**, call center coordinator.

RESOURCE

For more on the Emergency Contraceptive Connection, contact:

- **Kay Scott**, Planned Parenthood of Georgia, 100 Edgewood Ave., Suite 1604, Atlanta, GA 30303. Telephone: (404) 688-9305, extension 312. Fax: (404) 688-0621. Web site: www.ecconnection.org.

The computer also allows the agency to track usage features, such as number of calls, average age of patient, and other items for efficient use of statistical information.

To cover the cost of the service, Planned Parenthood of Georgia charges a $40 fee, made payable by credit card over the telephone. While the need for a credit card does limit the access to the hotline, agency officials believe the hotline is meeting the needs of many Georgia women. Women who do not have credit card access may visit one of the clinics, which offer subsidized and sliding-scale care, Scott notes.

Unless the Preven Emergency Contraceptive Kit (Gynétics, Belle Mead, NJ) is specifically requested, the hotline calls in a prescription for a single pack of birth control pills. The hotline provides the instructions on how to take the pills for emergency contraception. Callers in rural areas especially like the privacy of picking up a package of birth control pills because they are not labeled as emergency contraception, Scott says.

Opening the door

Although a physical exam is not required, each caller is reminded to follow up with her health care provider or drop by a Planned Parenthood clinic for a visit, she says. That advice, given at the end of each hotline session, is particularly important when it comes to those callers who use no regular form of birth control. While the agency does not limit the number of times a woman can access emergency contraception, it does point out that ECPs are not intended as a regular form of birth control. Some have wondered if such unlimited availability encourages women to be irresponsible in protection against pregnancy.

"We use the analogy that we all wear seat belts, but that it doesn't give us license to drive like maniacs," counters Scott. "Our goal is that every woman of childbearing age has emergency contraception in her medicine cabinet, so if she needs it, it's there." ■

Contraceptive options to seek FDA approval

Monthly injectable, IUS move toward acceptance

Pending their approval by the U.S. Food and Drug Administration, two contraceptive methods, the combined monthly injectable and the levonorgestrel intrauterine system (IUS), soon may be available to American women.

Pharmacia & Upjohn of Bridgewater, NJ, has filed an amended New Drug Application with the FDA for Lunelle, a combined hormonal injection method, confirms **Kristin Elliott**, public relations director for the company's diversified products division.

The amended application includes information from a recently completed clinical trial, whose findings were scheduled to be presented at the annual Clinical Meeting of the American College of Obstetricians and Gynecologists in Philadelphia in May. **(For details on the clinical trial, see *Contraceptive Technology Update,* January 1998, p. 3.)**

"We are very hopeful that the chronology on this will move forward, that we would receive an approval as early as this fall, and the launch would follow that," says Elliott.

Berlex Laboratories of Wayne, NJ, is evaluating the levonorgestrel IUS and expects to file with the FDA later this year, says **Wendy Neininger**, company director of corporate communications. Berlex is an American subsidiary

EXECUTIVE SUMMARY

Two contraceptives, the combined monthly injectable and the levonorgestrel intrauterine system (IUS), may be headed to the United States as manufacturers move through the drug-approval process.

- Pharmacia & Upjohn has filed an amended New Drug Application with the U.S. Food and Drug Administration for the monthly combined injectable, Lunelle. Marketed in other countries as Cyclofem, the method has demonstrated high contraceptive efficacy.
- Berlex Laboratories is evaluating the levonorgestrel IUS and expects to file with the FDA this year. The levonorgestrel IUS is marketed outside the U.S. as the Mirena by Berlex's parent company, Schering AG of Berlin, Germany. It offers contraceptive and therapeutic capabilities.

of Schering AG, a global pharmaceutical company in Berlin, Germany. Schering acquired the levonorgestrel IUS technology when it purchased the Finnish company Leiras Oy in 1996. Leiras and the New York City-based Population Council served as co-developers of the hormonal contraceptive device.

Neininger declined to give a time frame for the company's filing with the FDA. While the levonorgestrel IUS is approved for use in other companies, such approval does not mean an automatic endorsement from the U.S. regulatory agency, she notes.

Different from Depo

Family planners may recognize Lunelle as Cyclofem, which was developed by the United Nations Development Programme/United Nations Population Fund/World Health Organization/World Bank Special Programme of Research, Development, and Research Training in Human Reproduction in Geneva, Switzerland. The drug contains 25 mg of depot medroxyprogesterone acetate (Depo-Provera, or DMPA) and 5 mg of estradiol cypionate, and it is administered once a month via injection.

Pharmacia & Upjohn, which holds U.S. marketing rights to the drug, filed its original application with the FDA in September 1997. The amended application now contains the results of the U.S. clinical trial, which enrolled more than 1,160 women in more than 40 sites.

Lunelle administered monthly

In amending the new drug application, Pharmacia & Upjohn also changed the brand name of the drug from Cyclo-Provera to Lunelle. The name change offers a clear distinction from DMPA, another method marketed by the company, and the new monthly injectable.

DMPA and Lunelle are very different drugs, notes Elliott. DMPA is a progestin-only method and is administered four times a year. Lunelle contains both an estrogen and a progestin and is administered on a monthly basis. While Lunelle contains the same progestin as DMPA, the dose received over time is much lower. **(Read more about monthly combined injectables in *CTU*, June 1996, p. 71.)**

Medical eligibility criteria issued by the World Health Organization (WHO) in Geneva, Switzerland, lists Cyclofem as appropriate for most women who want effective, reversible contraception and who are not at risk for most cardiovascular complications.[1] Its estrogen has a shorter lifespan and is less potent than those found in combined oral contraceptives, so its restrictions vary somewhat from those for oral contraceptives.

For example, the WHO guidelines say the advantages outweigh the risks for smokers under age 35 or for light smokers over 35, as well as for those with mild hypertension (blood pressure below 160/100), current or medically treated gallbladder disease, or mild cirrhosis (compensated). However, the WHO states that the risks outweigh the advantages for heavy smokers (more than 20 cigarettes daily) over 35, those with a history of hypertension or blood pressure 160/100 or 180/110, and those with severe cirrhosis (decompensated), or liver tumors (benign).

Contraceptive efficacy is extremely high with Lunelle, with failure rates of approximately 0.2%,[2] says **Andrew Kaunitz**, MD, professor and assistant chair of the Department of OB/GYN at the University of Florida Health Sciences Center in Jacksonville. In contrast to DMPA, users often experience regular cycles[2] and a rapid return to fertility,[3] he notes.

Multiple benefits of IUS

The levonorgestrel IUS, marketed as the Mirena in European and Asian countries, is a T-shaped device with a hollow barrel filled with 52 mg of levonorgestrel. The device is approved for five years in the markets in which it is now available. **(*CTU* provided a complete overview of the IUS in January 1997, p. 4.)**

Aside from providing exceptional contraception, the levonorgestrel IUS has several exciting potential therapeutic applications, says **David Grimes**, MD, vice president of biomedical affairs at Family Health International in Research Triangle Park, NC.

"It has been shown to be effective in treating idiopathic menorrhagia [heavy bleeding][4] as well as dysfunctional uterine bleeding [without underlying pathology].[5] It has been found useful in treating abnormal bleeding associated with adenomyosis of the uterus," he says.[6]

In addition, the levonorgestrel IUS has been used as part of hormone replacement therapy, providing the progestin directly to the endometrium, rather than systemically, Grimes says.[7]

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Contraceptive coverage act returns this year

By the time you read this issue of *Contraceptive Technology Update,* the wheels should be in motion for the reintroduction of a U.S. Congressional bill of epic importance: the Equity in Prescription Insurance and Contraceptive Coverage (EPICC) Act of 1999.

The legislation, which failed to pass the 1998 session, again will be sponsored by Sens. Olympia Snowe (R-ME) and Harry Reid (D-NV) and Reps. Jim Greenwood (R-PA) and Nita Lowey (D-NY). The measure calls for equitable coverage of prescription contraceptive drugs, devices, and services under health plans. It would require insurers already providing prescription coverage and outpatient services to include prescription contraceptive drugs and devices approved by the U.S. Food and Drug Administration as part of their health plans.

Although Congress did not pass EPICC legislation last year, it did enact a mandate that federal employee health plans provide insurance coverage for contraceptive drugs and devices if the plans cover prescription drugs.

Many linked the emergence of the two bills as a response to the boom of the impotence drug Viagra, which was quickly included in many health plans. **Marilyn Keefe**, director of public policy for the National Family Planning and Reproductive Health Association in Washington, DC, disputes that assessment.

"It makes it seem that coverage of Viagra is so outrageous, when I'm not sure that that is really the issue," she observes. "The issue is that women need access to this basic preventive health service [for which] insurers have been providing fairly poor coverage for decades."

Adding contraceptives

Until 1978, many insurance policies did not cover maternity care, notes **Rachel Benson Gold**, assistant director for policy analysis at the Washington, DC, office of the Alan Guttmacher Institute. This issue was addressed in the Congressional passage of the Pregnancy Discrimination Act.

"You want the debate [now] to be about how family planning is a mainstream basic health care service and that contraceptives are the only class of drugs that seems to be routinely excluded from health plans," Keefe says. "Health plans are very good at covering surgical procedures, like sterilization [which is the most popular method of birth control], are fairly good at covering abortion services, but they are just not totally on track at covering preventive health care services like contraception."

EXECUTIVE SUMMARY

Women's health issues come to the forefront of national politics this summer as the Equity in Prescription Insurance and Contraceptive Coverage Act of 1999 hits Congress.

- First introduced in 1998, the legislation seeks equitable coverage of prescription contraceptive drugs, devices, and services under health plans. It also would require insurers already providing coverage for prescriptions and outpatient services to include as part of their health plans prescription contraceptive drugs and devices approved by the U.S. Food and Drug Administration.
- Many insurance plans cover no reversible contraceptive methods, and those that do typically don't include all FDA-approved prescriptive methods. While 97% of traditional fee-for-service plans routinely cover prescription drugs, only one-third of them cover oral contraceptives.

Many insurance plans, including half of traditional fee-for-service and preferred provider organizations, cover no reversible contraceptive methods.[1] Even plans that do provide some contraceptive coverage typically do not cover all FDA-approved prescriptive methods. While 97% of traditional fee-for-service plans routinely cover prescription drugs in general, only one-third of them cover oral contraceptives.[1]

The estimated maximum cost to cover the full range of FDA-approved reversible medical contraceptives in health plans that do not currently cover them is just $21.40 per year.[2] Of that figure, $17.12 would be employers' costs and $4.28 employees' cost. The added cost to employers amounts to just $1.43 per month per employee, a 0.6% increase. The cost would be less for those plans that already cover some of the methods.

Public support for bill

A 1998 survey shows that nearly three-quarters of privately insured adults support contraceptive coverage, even if it raises costs $1 to $5 each month.[3]

Several organizations, including the American College of Obstetricians and Gynecologists in Washington, DC, and the American Medical Association in Chicago, supported the 1998 bill and are expected to lobby for the passage of the 1999 bill, as well.

How can family planners become involved? Keefe suggests providers contact their Congressional representatives and senators and ask them to cosponsor the bill when it is introduced. "Basically, just let [representatives] know that this situation is not fair, it's not equal, and it's time to change it in this legislative session," she says. "It is something that American women are not going to continue to put up with, though certainly we have for decades."

(See what states are doing about contraceptive coverage, at right.)

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States address coverage for contraceptives

More than half of U.S. state legislatures have addressed insurance coverage for prescription contraceptives this year, but the jury is still out on which bills will be signed into legislation.

"Several of the bills are moving, and moving quickly, and seem to be doing well," observes **Rachel Benson Gold**, assistant director for policy analysis with the Washington, DC, office of the Alan Guttmacher Institute. "It was a major priority for the state legislatures this year."

The state of Georgia has joined Maryland as the second state with a comprehensive contraceptive coverage law. The Georgia law, which mandates that health policies covering prescriptions include prescription contraceptives as well, now has been signed into law.

The Washington office of the Alan Guttmacher Institute reports that 60 bills concerning contraceptive coverage had been introduced in 31 states as of *Contraceptive Technology Update*'s press time. That compares favorably with 1998, when 20 states introduced such bills.[1] Bills in California, Hawaii, Illinois, North Carolina, Vermont, Washington, and Nevada had passed at least one house and were still in play. Alaska, Connecticut, New Jersey, New York, and Oklahoma had bills passing at least one committee, as did Florida, with a bill requiring coverage of oral contraceptives only.

Bills on contraceptive coverage were defeated or died at the end of sessions in Idaho, Indiana, Nebraska, New Mexico, and Utah. Bills were introduced — but no action was taken — in Louisiana, Maine, Massachusetts, Missouri, Montana, New Hampshire, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, and West Virginia.

EXECUTIVE SUMMARY

Coverage for prescription contraceptives has been a hot topic in state legislatures this year, with more than 25 states introducing bills on the subject.

- Georgia has joined Maryland as the second state with a contraceptive coverage law.
- The issue of insurance coverage for contraception also has raised requests for conscience clauses to allow plans, providers, employers, and even pharmacists to claim conscientious objections to providing such access.

Some of the state bills are modeled after the federal Equity in Prescription Insurance and Contraceptive Coverage Act, whereby if coverage is offered for prescription drugs, prescription contraception must be covered as well, says **Marilyn Keefe**, director of public policy for the National Family Planning and Reproductive Health Association in Washington, DC. Other bills appear to have less substance. The focus should remain on the fact that prescription contraceptives are the only class of drugs routinely excluded from health plan coverage, she says.

Offerings vs. mandates

Last year, Maryland became the only state to pass legislation requiring private insurers to provide comprehensive coverage for contraceptives if they covered the cost of prescription drugs. Virginia and Hawaii passed laws that require health insurers to offer employers the option of including coverage in the benefit plans for their employees, but the laws do not mandate coverage.

A mandate to offer, which is included in the Virginia and Hawaii law, says the insurer has to offer the coverage to the employer, Gold explains. It is then up to the employer to decide whether to include contraceptive coverage in the policy he or she purchases for employees.

An actual contraceptive coverage mandate requires the coverage to be included in the policy the employer buys. Mandates often are adopted at the state level, says Gold, who points to state insurance mandates for such health issues as mammograms and preventive health care for children.

The introduction of state contraceptive coverage legislation also has raised issues of conscience, as certain insurance providers, employers, and even pharmacists look to claim conscientious objections in providing certain or all contraceptive methods.

At *CTU* press time, an amendment had been added to the North Carolina Senate contraceptive equity bill that would allow employers to exclude coverage of emergency contraception and mifepristone. The Washington, DC-based Association of Reproductive Health Professionals has asked that the amendment be rejected and points to the important public health benefits of providing emergency contraception.[2]

New Jersey legislators are considering a proposed conscience clause by pro-life pharmacists who wish to claim conscientious objection to dispensing emergency contraception, which they claim is an abortifacient.[3]

"The contraceptive coverage issue highlights several fault lines at the intersection of religious beliefs and the provision of health care services," Gold writes in a special series of articles that examined key policy questions on the subject of contraceptive coverage.[4] Individual providers, health care plans, and employers all may seek legislation to invoke conscientious objections.

Attention should focus on making sure women have access to services, Gold says. Many creative solutions have been devised to give those who desire an "arm's length" to contraceptive coverage to opt out of contraceptive coverage plans, while making sure women have clear access to the full complement of approved contraceptive devices.

One example that respects beliefs but ensures access is the contraceptive coverage bill introduced in the state of Washington. The bill would allow an individual employed by a religious employer to bypass the employer and buy contraceptive coverage directly from the insurer at the same cost as could the employer. The employer could exercise his or her religious beliefs, but the employees who need coverage still would have access to it.

The contraceptive coverage bill for federal employees, which passed last year, included an exemption for religious health plans. Because employees in the federal system are allowed to choose plans, they simply could choose one that includes contraceptive coverage, Gold says.

"What is key to that situation is notification and information, because you can only make those informed choices if you have the information to make them," she observes. "I think that set us down the path of saying, 'We need to keep our eye on the issue of access on the other side.'"

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ASK THE EXPERTS

Answering questions on galactorrhea, DMPA

Question: What is your clinical experience with galactorrhea, a whitish or greenish discharge in a woman who is not breast-feeding? Is use of the drug depot medroxyprogesterone acetate (DMPA) associated with galactorrhea? How long after breast-feeding has stopped should women be concerned about galactorrhea? — **Alice Burin**, NP, Arlington (VA) County family planning clinic

Leon Speroff, MD, professor of OB/GYN at Oregon Health Sciences University, in Portland, addresses these questions. For more information about galactorrhea, readers may want to consult *A Clinical Guide for Contraception* (2nd edition, Baltimore, MD, Williams & Wilkins, 1996), co-written by Speroff and Philip Darney, MD, professor of OB/GYN and reproductive sciences at the University of California at San Francisco.

"Galactorrhea is not associated with the use of DMPA. Prolactin gene transcription is stimulated by estrogen and mediated by estrogen-receptor binding to estrogen-responsive elements. This activation by estrogen requires interaction with Pit-1 in a manner not yet determined. The increase in prolactin during pregnancy parallels the increase in estrogen beginning at seven to eight weeks gestation, and the mechanism for increasing prolactin secretion is believed to be estrogen suppression of the hypothalamic prolactin-inhibiting factor, dopamine, and direct stimulation of prolactin gene transcription in the pituitary.[1,2]

"Although requiring estrogen for prolactin secretion, prolactin stimulation of breast milk production is prevented by progestational agents and pharmacologic amounts of estrogen. Only colostrum (composed of desquamated epithelial cells and transudate) is produced during gestation. Full lactation is inhibited by progesterone, which interferes with prolactin action at the alveolar cell prolactin receptor level. Both estrogen and progesterone are necessary for the expression of the lactogenic receptor, but progesterone antagonizes the positive action of prolactin on its own receptor, while progesterone and pharmacologic amounts of androgens reduce prolactin binding.[3-5]

"In the mouse, inhibition of milk protein production is due to progesterone suppression of prolactin receptor expression.[6] The effective use of high doses of estrogen to suppress postpartum lactation indicates that pharmacologic amounts of estrogen also block prolactin action.

"Progesterone can directly suppress milk production. A nuclear peptide (a co-repressor) has been identified that binds to specific sites in the promoter region of the casein gene, thus inhibiting transcription.[7] Progesterone stimulates the generation of this co-repressor. After delivery, the loss of progesterone leads to a decrease in this inhibitory peptide.

"The principal hormone involved in milk biosynthesis is prolactin. Without prolactin, synthesis of the primary protein, casein, will not occur, and true milk secretion will be impossible. The hormonal trigger for initiation of milk production within the alveolar cell and its secretion into the lumen of the gland is the rapid disappearance of estrogen and progesterone from the circulation after delivery.

"For these reasons, exposure to high levels of progestational agents, such as DMPA, is not associated with the clinical problem of galactorrhea.

"If galactorrhea has been present for six months to one year after breast-feeding, or hyperprolactinemia is noted in the process of working up menstrual disturbances, infertility, or hirsutism, the probability of a pituitary tumor must be recognized and an appropriate evaluation pursued. This recommendation has evolved empirically, with providers knowing that many women have the persistence of galactorrhea for many months after breast-feeding. Therefore, the rule is a soft one. The exact numbers have never been established by appropriate studies. Thus, there is plenty of room for clinical judgment with this problem."

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CTUPDATES

News ■ Resources ■ Events

Health fairs to focus on adolescent needs

How would you like to reach teens with important prevention information about pregnancy, sexually transmitted diseases, and HIV before they enter your exam room? A group of national health associations has launched a community awareness initiative to focus on these issues.

Two Washington, DC-based advocacy groups, the Association of Reproductive Health Professionals (ARHP) and the Religious Coalition for Reproductive Choice, recently held a briefing on adolescent health for U.S. Congressional members and staff members. The event was co-sponsored by the Congressional Caucus on Women's Issues, the Congressional Black Caucus, the Congressional Hispanic Caucus, the Progressive Caucus, and the Congressional Asian Caucus.

Not only did the briefing give Congressional members an overview of the risks teens face when it comes to pregnancy, STDs, and HIV, it provided a way to take the message to the streets through the concept of community-based adolescent health fairs. Each briefing attendee received a comprehensive kit, complete with sample announcements, patient education handouts, and other planning tools to help Congressional members sponsor adolescent health fairs in their districts.

Each year, almost a million teen-age girls become pregnant. Three million teens — about one in four sexually experienced adolescents — acquire an STD each year. By the end of 1997, there were nearly 3,000 teen-agers known to have full-blown AIDS. While professionals within the family planning community are acutely aware of the health risks faced by adolescents, the same level of knowledge is not evidenced in the general population, points out **Trent MacKay**, MD, MPH, the incoming chair of ARHP.

"Since we are the ones who know this material and are probably in the best position to explain it to others, I think we have a real obligation to speak directly to adolescents and to educate other adults who can influence adolescent behavior," MacKay says. "It is extremely important that we spread the word about the risks and the ways to prevent teen-age pregnancy, STDs, and HIV."

ARHP will serve as a resource to link regional and local reproductive health care providers with Congressional staff who will plan the health fairs, says **Wayne Shields**, president of ARHP.

For more details, contact: Johanna Chapin, Association of Reproductive Health Associates, 2401 Pennsylvania Ave. N.W., Suite 350, Washington, DC 20037-1718. Telephone: (202) 466-3825. Fax: (202) 466-3826. E-mail: JBChapin@aol.com. ▼

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Conference focuses on older women's health

Get the latest research and clinical information on the aging woman at the "Advances In Health Care for Women Over 40" conference sponsored by Contemporary Forums and scheduled for Aug. 2-6 in Jackson Hole, WY.

Issues to be covered include a primary care perspective on exploring lifestyle and psychosocial issues, as well as physical concerns and challenges for women as they age.

Other conference sessions will include up-to-date information on the relationship between hormone replacement therapy and Alzheimer's disease, osteoporosis, and cardiovascular disease; new hormone replacement therapy delivery systems; and a look at effective alternative and complementary therapies for menopause management.

For additional information on the conference, contact: Contemporary Forums, 11900 Silvergate Drive, Dublin, CA 94568-2257. Telephone: (925) 828-7100. E-mail: hlth@cforums.com. Web: http://www.cforums.com. ■

CE objectives

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• Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services **(See "Contraceptive options to seek FDA approval," p. 65, and "Answering questions on galactorrhea, DMPA," p. 70.)**

• Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.

• Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "One call does it all for women seeking ECPs," p. 64.)** ■

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