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Direct-to-consumer advertising affects provider/patient relationship

Patients more aware of prescription drugs — Are they better educated?

A young woman enters your office, clutching an ad torn from a popular magazine. She asks for an oral contraceptive (OC) by name. What do you do?

If you are seeing more of those types of requests, you are not alone. **Kathy Zubik**, CRNP, a nurse practitioner in the student health services facility at Elizabethtown (PA) College, reports an increase in requests for Ortho Tri-Cyclen (Ortho-McNeil Pharmaceuticals, Raritan, NJ). The company received approval in 1997 for use of the drug as a treatment for moderate acne from the U.S. Food and Drug Administration (FDA), and it has marketed the indication.

"I never have had requests as often for a particular brand of OC as with this," Zubik says. "We are a small liberal arts college [1,500 students] and are limited in the number of OCs we can carry here for distribution to students, but I did add Tri-Cyclen to our formulary. It now is the No. 1 choice of mine for 'new starts.'"

Cynthia Waldron, PA-C, manager of gynecologic services for Planned Parenthood / Preterm of Greater Boston, also notes an upturn in requests, the majority of which are generated by magazine advertising aimed at

EXECUTIVE SUMMARY

More patients are requesting brand-specific drugs following an increase in direct-to-consumer advertising of prescription pharmaceuticals.

- The number of television advertisements of Rx drugs has jumped since last year, when the Food and Drug Administration (FDA) offered proposed guidance to permit broadcast commercials to forego the "brief summary" of safety and efficacy information.
- The FDA's division of drug marketing, advertising, and communications in Rockville, MD, oversees such advertising and ensures it is truthful, balanced, and accurate.
- While providers may feel pressured to prescribe medications, they also see such requests as a way to involve patients more in their own care.

young women. The effects are troubling, she says. "I have found brand-specific requests difficult to deal with. I do not view OCs in the same manner as choosing a brand of toothpaste, for example."

The ideal scenario is one in which prescribing clinicians choose what they feel is best for patients, she says. "On the other hand, it usually is fine and makes the patient feel satisfied if we can prescribe the pill she requests. It is important to inform each patient, however, that they may not have the favorable experience promoted in the advertisement and that any low-dose OC will give the majority of women a favorable outcome."

Ad dollars redirected

Direct-to-consumer ads have spurred the recent increase in brand-specific requests for prescription drugs. While print consumer pitches for Rx drugs have been on the scene for some time, proposed guidance issued by the FDA in August 1997 allows pharmaceutical companies to more easily broadcast product claim commercials on TV and radio.

That move has caused a dramatic result: Half of all direct-to-consumer advertising dollars spent by pharmaceutical companies during January and February 1998 were directed to television ads, nearly twice the share spent on television last year, according to Scott-Levin of Newton, PA, a marketing information firm.[1] Total spending for such advertising reached $139 million during that two months. Last year, pharmaceutical companies spent more than $1 billion on direct-to-consumer advertising, the firm estimates.

The change is making its presence known in providers' offices. Prior to the FDA guidance, 41% of physicians participating in a national survey observed an increase in patients' requests for brand name drugs, according to IMS Health, a Westport, CT, pharmaceutical information firm.[2] Since the change, 65% surveyed to date have observed an increase in such requests.

With the increase in advertising comes potential for violations of the U.S. Food, Drug, and Cosmetic Act, which regulates provider and consumer prescription drug advertising. According to information posted by the FDA's Freedom of Electronic Information Office, 125 companies have been cited for violations in 1998. Six were cited specifically for violations connected with contraceptive information they disseminated. **(Be sure to read the January *Contraceptive Technology Update* for an overview of the violations.)**

Before the change in FDA guidance, most of the commercials seen on TV were "reminder" ads, says **Norman Drezin**, RPh, JD, deputy director of the FDA's division of drug marketing, advertising, and communications in Rockville, MD. Reminder ads are allowed to mention a drug's name but cannot specifically state its use.[3] Another form of advertising, the "help-seeking ad," does not give a brand name but only mentions that treatments are available. Those types of commercials, which Drezin characterizes as "see your doctor" ads, cannot state or imply the name of a product but are allowed to mention the manufacturer's name.

By federal law, prescription drug ads that make product claims must contain certain information about the drug's side effects, contraindications, and effectiveness. Known as the "brief summary," such information has been addressed in print ads by including the risk-related sections of drug labeling along with the advertising copy. Providing the same level of information in a 30- to 60-second broadcast advertisement, however, can be a daunting task, given the time and format constraints.

As consumers have become more involved in their health care, they have sought increased information on prescription drugs. Due to the confusion caused by broadcast ads held to such statements as "There's treatment for [fill in the blank] — see your doctor," the FDA issued a draft guidance for public comment in August 1997.

The proposed guidance, which companies are now using to produce broadcast advertising, call for the manufacturer to ensure easy access to full product labeling in lieu of the brief summary.[4] Companies can provide access through a variety of means, such as offering a toll-free number for consumers to get product information by mail,

COMING IN FUTURE MONTHS

- Women who smoke: How to help them quit
- Client-centered, interactive HIV/STD counseling
- Screening female teens for chlamydia infection
- Curbing second thoughts on sterilization during counseling
- Boosting use of female condoms

fax, or phone; referring to print ads or a Web address that carry the brief summary of the product labeling; or referring consumers to health care providers for more information.

In a product claim ad, fair balance of information is important because of its impact on a consumer, stresses Drezin. "Prescription drugs are not magic bullets; they do have side effects, and they are not for everyone. Consumers need to understand that these are drugs, and they do have effects. Some of them you want, and on the other hand, there are some you may not want. Checking with their provider is the most important point."

While a national survey of physicians shows 71% believe consumer ads pressure providers to use medications they may not ordinarily, 60% agree it encourages patients to take a more active role in their health care.[5]

How can providers handle brand-specific requests if their formularies don't include the drug in question, or patients' insurance only covers certain brands?

In Hawaii, the major insurance carrier covers just four OCs, says **Rick Williams**, MD, medical director of the Women's Clinic in Pearl City. The choices usually are Loestrin 1/20 (Parke-Davis, Morris Plains, NJ), Tri-Levlen (Berlex, Wayne, NJ), Desogen (Organon, West Orange, NJ), and one other. If patients come in with a specific request for the "acne pill" or Ortho Tri-Cyclen, he uses this strategy: "Since the promotion talks about acne, I tell them that Desogen is just as good as any Ortho product. For patients without insurance, I prescribe Zovia 1/35 [Watson Laboratories, Corona, CA], which is kind of like generic Demulen."

Direct marketing can be classified as neither "good" nor "bad" in that it has aspects of both, observes **Constance Songer**, CRNP, RNC, a nurse practitioner at Gettysburg (PA) College's Health Center. As a health care provider, Songer says she likes using the teaching opportunities to point out the pros and cons of the advertising in question, as well as why a particular drug may or may not be appropriate for an individual patient. There are pitfalls as well, she points out.

"There are those few patients who are convinced that the marketing information is indisputably accurate and that providers are uninformed if they disagree with the patients' requests," Songer says. "These patients would probably be difficult anyway, but direct marketing has added to their confusion and fear and our stress level. It is important to me to dredge up that last iota of patience and diffuse both."

Williams uses patients' questions on specific pills to educate women on the non-contraceptive benefits of oral contraceptives. (**See his patient handout on OCs, enclosed in this issue**, or visit his Web site: http://www.rickmd.com.) He says consumer advertising can only bode well for providers. "Informed consumers are ultimately better for the provider. It does take more time, but that is time well spent."

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Low-dose OCs don't add to heart attack risk

The evidence grows for the safety of low-dose (under 50 mcg estrogen) oral contraceptives (OCs) following release of new data showing no increased risk for heart attack among women with no previous risk of coronary heart disease.[1]

Researchers with the northern and southern California units of Kaiser Permanente Medical Care Program in Oakland and Pasadena and the University of Washington in Seattle conducted separate population-based case-control studies and pooled the data for the comprehensive report.

The studies were designed to be combined from the beginning to confirm consistent findings between the two sites, as well as to gain a greater degree of precision in determining the estimated risk associated with OCs, says **Stephen Sidney**, MD, MPH, associate director for clinical research at Kaiser-Permanente's Oakland site.

As cases, the studies included women 18 to 44 with incidents of heart attack but no prior incident of ischemic heart disease or cerebrovascular disease. Women in the case and control groups were interviewed about OC use and cardiovascular risk

EXECUTIVE SUMMARY

Newer forms of oral contraceptives with lower doses of estrogen do not increase women's risk of heart attacks, according to a large study from two West Coast institutions.

- The study falls in line with current research affirming the safe use of oral contraceptives among women without previous risk of coronary heart disease.
- Two findings — a link between reduced risk and past pill use, and no elevation of risk among current users who smoke — need further study to substantiate them, researchers conclude.

factors. The analysis included 271 cases and 993 controls.

In the pooled analysis, there was no evidence of an increased risk of heart attack associated with the use of OCs, a finding consistent with most other recent studies.[2-6]

Results from a recent multinational study from the World Health Organization (WHO) in Geneva, Switzerland, also showed minimal risk for young women who have no previous identified risk.[7] However, the WHO study did report an elevated risk of heart attack among pill users who smoke or have high blood pressure. **(See *Contraceptive Technology Update*, July 1997, p. 85, for full results of the WHO study.)**

One of the biggest differences in the design of the WHO study is its inclusion of women who were not screened for cardiovascular risk factors, Sidney says. The WHO study did find that nonsmoking women who had had a blood pressure check prior to taking OCs had no increased risk of heart attack, a finding that is consistent with the U.S. study.

One intriguing finding from the U.S. study is the association of past OC use with a statistically significant decrease in the risk of heart attack, says **Ramona Slupik**, MD, assistant professor of OB/GYN at Northwestern University in Chicago. Is it possible there was a selection bias in the study, and people with different risk factors received different pills or didn't receive the pill at all? The answer is no, because the cardiovascular risk factors were similar in cases and controls, she notes. Unmeasured factors, such as a healthy lifestyle, may have confounded the results, researchers say. Other studies are needed to tease out associated factors, she says.

While the U.S. study showed no increased risk of heart attack among current OC users who smoke, the body of previously published evidence clearly supports the dangers of combining the two, says Sidney. "Providers should absolutely counsel women who are smokers that they need to stop. I would not prescribe OCs to a woman who is a smoker and is not going to stop."

The researchers note the limitations of the study, which include possible response, recall, and diagnostic bias, Slupik points out. Until further evidence to support the OC/smoking finding becomes available, Slupik agrees with Sidney that providers should continue to counsel heavily for smoking cessation prior to OC use.

For women with high blood pressure, providers should use clinical judgment in assessing OC use, Sidney states. High blood pressure does not automatically rule out pill use, he says. Providers must take into account a number of factors, including the risk of pregnancy and the medical problems that may arise from it.

"I think blood pressure certainly should be considered, with a tendency probably to not put somebody on OCs if they have untreated high blood pressure," Sidney observes. "I don't think we know a lot about treated blood pressure, so it really comes down to individual judgment."

What's next in research?

Researchers at Kaiser-Permanente are now looking at OC use and venous thromboembolism, an issue that has captured the interest of investigators around the world. (Such investigations have looked at risks associated with estrogen dose and differences in second- and third-generation progestins. **For details, see *CTU*: January 1996, p. 6; April 1996, p. 41, p. 47; November 1996, p. 142; and December 1996, p. 149.**)

"I think all the studies that have been done thus far suggest that there really is an increased risk with OC use, and we are studying that now in the same Kaiser population," Sidney reports. "I think clearly there is evidence coming out that there's a genetic component to this risk, that women who have genetic predisposing conditions may be at higher risk of blood clots."

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Women plan condom use after sterilization

Women are not only hearing the HIV / AIDS prevention message, they are putting it into practice by planning condom use after sterilization. Of nearly 3,000 women who chose tubal sterilization at the Baylor College of Medicine in Houston from 1991 to 1996, 42% reported plans for future condom use.[1]

A cross-sectional study reveals steady and significant growth of planned condom use among women choosing the permanent form of birth control.

Communicating the need for continued protection against HIV / AIDS and other sexually transmitted diseases (STDs) is doubly important when women are counseled prior to choosing sterilization, says **Amy Pollack**, MD, MPH, president of AVSC International in New York City.

It has been documented that women who receive tubal sterilizations visit their family planning providers less often because they no longer require birth control supplies,[2] Pollack notes. Therefore, the opportunity for stressing the need for HIV / AIDS and STD protection comes before the procedure is done, she stresses.

Getting the disease prevention message across is crucial when one considers a large majority of women report sterilization as their chosen method of contraception, says **Haleh Sangi-Haghpeykar**, PhD, assistant professor in the contraceptive research and development division and lead author of the Baylor study. "It is estimated that in the U.S. alone, more than 1 million tubal sterilizations are performed each year.[3] Although sterilization is very effective at prevention of pregnancy, it does not prevent exposure to STDs," she says.

Women who are older and in long-term monogamous relationships may think they are at low risk for HIV / AIDS and STDs. That belief may keep them from planning condom use once they undergo tubal sterilization, and they need to understand that their partners may continue to place them at risk, she says. "[The women] might be faithful, but their partners may not. In this day and age, I think prevention is an issue that everyone should be concerned about, not just a certain population of non-married, single young women."

Little data available

There is a shortage of research on women's use of HIV / AIDS and STD prevention strategies following sterilization, Sangi-Haghpeykar notes. The Baylor researchers decided to question patients in the Houston family planning clinic over six years to learn more about their plans for condom use following tubal sterilization.

Women at the clinic receive a standard counseling and educational session, where information is presented on the importance of condom use. After the physical exam, patients are asked to complete a questionnaire, which includes the

EXECUTIVE SUMMARY

Women plan to use condoms after tubal sterilization to protect themselves against HIV/AIDS and other sexually transmitted diseases (STDs). This finding from a Houston-based study is another sign the protection message is being received.

- Because evidence shows that women return less frequently to reproductive health care providers after sterilization, women considering sterilization need to be informed fully upfront that the permanent form of birth control offers no STD protection.
- More than a million U.S. women choose sterilization each year. Although these women may not require continued family planning services, condoms should be made easily accessible for STD protection.

following question: "Do you plan to use condoms during intercourse in the future to protect yourself and/or others from HIV infection and other sexually transmitted diseases?"

The 2,782 women who received tubal sterilizations at the clinic ranged in age from 18 to 51. One-fifth of the women had a known risk factor for HIV. Nearly one-fourth of the women reported regular condom use for contraception or disease protection during the three months before sterilization.

Over the six-year period, planned condom use increased steadily, from 32% in 1991 to 51% in 1996, with this increase occurring regardless of age, marital status, or ethnic background. Of the 646 women who used condoms before sterilization, nearly half indicated no plans to do so after the procedure. As a result, 11% of the total sample experienced an increased risk for disease exposure.

Using multiple regression analysis to examine the association between condom use and various characteristics, researchers found that factors associated with condom use were:

- younger age;
- black ethnicity;
- unmarried;
- previous STD;
- no steady partner;
- higher number of previous sexual partners;
- use of condoms for disease protection in the past;
- lack of partner involvement in the decision to undergo sterilization.

Although the study does not track actual condom use after sterilization, the results show that more women plan to put disease prevention into practice following the procedure, says Sangi-Haghpeykar.

"Counseling does make an effect. It has been shown in other work,[4] and I'm sure it applies to this population as well, that if women are really counseled about the importance of condom use, they are more likely to use it," she says.

Family planners may want to consider encouraging women to return to the clinic for condom supplies after sterilization, Sangi-Haghpeykar suggests. By placing a basket of free condoms in the waiting room, women can stop by for supplies at their convenience.

"Somehow, we must provide access to this prophylactic method," she says. "Women have to understand that they have to continue to use condoms, and not just for a while."

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Options expand in wait for mifepristone arrival

As the wait continues for the U.S. introduction of mifepristone, providers are considering other options of very early abortion.

The Danco Group in New York City, which is bringing the drug to the American market, is arranging manufacturing details and getting information to the U.S. Food and Drug Administration (FDA) in hopes of securing final agency approval by the end of 1999, reports **Christina Horzepa**, a spokeswoman for the Population Council, also in New York City. The council, which holds the patent for the drug, has licensed Danco to manufacture and market mifepristone in the United States.

Just more than half of obstetricians/gynecologists and 45% of family practice physicians say they would offer mifepristone if it is approved, according to a national survey commissioned by

EXECUTIVE SUMMARY

Interest in other options in early abortion is increasing, as the wait continues for the U.S. introduction of mifepristone.

- The group that will manufacture and market the drug hopes for final Food and Drug Administration (FDA) by the end of 1999. More than half of OB/GYNs say they'll offer it when it's introduced.
- Methotrexate, which already has FDA approval, continues to be studied in medical abortion.
- Ultrasensitive urine tests and ultrasound advances now allow its use for very early surgical abortion. Manual vacuum aspiration offers a safe, effective option in medical abortion.

the Kaiser Family Foundation of Menlo Park, CA. An equal number of nurse practitioners and physician assistants say they also would offer the drug. (Is your facility considering offering mifepristone, methotrexate, or manual vacuum aspiration abortions? *Contraceptive Technology Update* will offer information from current providers in a special two-part series beginning next month.)

Nearly one in five OB/GYNs, including 11% of those who say they never perform surgical abortions, say they are likely to offer methotrexate abortions in the next year. Thirteen percent of nurse practitioners and physician assistants and 11% of family practice physicians report plans to offer the drug, according to the survey's findings.

Methotrexate, originally approved by the FDA as a cancer treatment in 1953, is no longer patented and is widely available. It was first used "off-label" in gynecology as a medical treatment for ectopic tubal pregnancies.

In the last five years, much research has focused on the intramuscular administration of methotrexate, followed by the vaginal administration of misoprostol, for use in medical abortions. A number of published studies have shown the safety and efficacy of the method, using 50mg/m^2 injection of methotrexate, followed by vaginal insertion of 800 µg of misoprostol tablets.[1-5] This regimen has proven effective in more than 90% of the cases. **(See C*ontraceptive Technology Update*, September 1998, pp. 114 and 119, for more details.)**

Early surgical options

Vacuum aspiration, which relies on suction to extract contents of a pregnancy from the uterus, has been the most common method used for first-trimester abortions. The advent of ultra-sensitive urine tests and ultrasound technology now allow women to seek abortions to do so earlier in their pregnancies. Manual vacuum aspiration has been used safely and effectively both for termination of pregnancy and management of incomplete abortion in dozens of countries for more than 20 years, says **Paul Blumenthal**, MD, associate professor in the OB/GYN department at Johns Hopkins University in Baltimore.

Interest in manual vacuum aspiration has increased since Jerry Edwards, MD, medical director of Planned Parenthood in Houston, published results using the technique in very early pregnancy.[6] With this technique, women can take a pregnancy test as soon as eight days after unprotected sex. Using ultrasound to confirm the results, the provider uses a handheld syringe and canula to remove the fertilized egg.

For the provider who does not perform abortions on a regular basis, the basic equipment required to perform manual vacuum aspirations is so minimal that it can be kept in a drawer in any GYN office, says **Carolyn Westhoff**, MD, DSc, medical director of family planning at Columbia Presbyterian Medical Center and associate professor of clinical OB/GYN and public health at Columbia University, both in New York City. Such availability can allow providers outside a dedicated clinic environment to take care of their patients in a safe, effective manner.

Another advantage to manual vacuum aspiration lies in its unobtrusiveness, Westhoff points out. It is less intimidating for some patients because it is less noisy and does not require a machine for the suction. Very early abortions also can be performed with electric suction, she notes, and many providers may chose to use it later in the trimester. The manual method affords another option, one that can be used outside a dedicated abortion clinic setting.

The range of improved options for very early abortion is one that both providers and women will welcome and may improve women's overall health by encouraging them to seek care earlier in their pregnancies, says **Felicia Stewart**, MD, director of reproductive health programs at the Kaiser Foundation. Such expansion of services are needed to overcome the barriers to abortion access. Eighty-four percent of all U.S. counties lacked an abortion provider in 1992.[7] One-quarter of women who have nonhospital abortions travel at least 50 miles from their home to the abortion facility.[8]

"These are all methods that are very safe and quite straightforward so that physicians in normal family practice settings or clinicians and physician assistants would find it feasible," Stewart notes. "That certainly could have the potential of increasing access to services."

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ASK THE EXPERTS

Frequent urination and Depo-Provera

Question: If a patient on Depo-Provera (DMPA) has frequent urination, could it be a warning sign of a more significant problem? What are the necessary steps in further treatment?

— **Barb Manion**, a provider at a Wisconsin family planning clinic

Andrew Kaunitz, MD, professor and assistant chair of the department of OB/GYN at the University of Florida Health Sciences Center in Jacksonville, FL:

Women using long-acting contraceptives, and sometimes their clinicians, often attribute unrelated health problems to the contraceptive. Frequent urination in a woman using DMPA is not likely related to her DMPA use. The "usual" causes of frequent urination, including urinary tract infections and diabetes, should be considered.

Anita Nelson, MD, medical director of the Women's Health Care Clinic, Harbor-University of California at Los Angeles Medical Center in Torrance, CA:

What you have described could be a sign of a urinary tract infection or diabetes. In fact, you could make some points here that methods of longer duration, such as the IUD, DMPA, and Norplant are very vulnerable to charges such as these. Anything a woman uses over time, including the pill, is often associated with changes. It is important to be alert to subtle changes, but a urinary tract infection or diabetes is not associated with DMPA.

Susan Wysocki, RNC, BSN, NP, president of the National Association of Nurse Practitioners in Reproductive Health in Washington, DC:

This is the second time I have heard this question. But I have never seen it referenced. I wonder if a possible cause could be hypoestrogenicity? My questions would be: Is her exam normal? Does the patient's vagina shows signs of decreased rugae? If she is having some vaginal atrophy, the tissue around her urethra could also be atrophic and therefore cause some urinary symptoms.

Question: When do you do a FSH (follicle-stimulating hormone) to confirm menopause in a perimenopausal woman using DMPA? Does she have to be off the DMPA first, and if so, how long? Or will the FSH rise regardless?

— **Margie DeLong**, CRNP, **Barb Korosi**, CRNP, **Jackie Amalong**, CRNP, Family Planning Association of Northeast Ohio in Painesville

Kaunitz: Regarding making the transition from DMPA to HRT, first of all, I am not aware that any data addresses this topic. Accordingly, my recommendations reflect clinical judgment.

Women who use DMPA in their late 40s/early 50s do not experience menopause in the conventional sense i.e., because they may already be amenorrheic, they will not experience the new onset of amenorrhea. Because DMPA suppresses hot flashes, these will not likely occur. Checking FSH levels is not necessarily helpful in this setting, for two reasons. First, menopausal [elevated] FSH levels may be suppressed [lowered] by DMPA. Second, in perimenopausal women, a single elevated FSH does not predict menopause; levels fluctuate markedly in this setting.

Here's the approach I use when women in their 40s or beyond have been using DMPA and are doing well on it. Women who are perimenopausal are often relatively hypoestrogenic. In addition, women who use DMPA are also relatively hypoestrogenic. Accordingly, I continue the DMPA and liberally supplement such women with estrogen (e.g. oral conjugated estrogen 1.25 mg daily, 1.25 of estropipate, estradiol 1 mg, or esterified estrogen 1.25 mg.) You also can employ lower doses of estrogen. Alternatively, you can use transdermal estrogen supplementation.

Family planning questions? 'Ask the Experts'

Do you have a question about a contraceptive method or procedure? Send your questions to "Ask the Experts," a recurring feature of *Contraceptive Technology Update*. We will include responses from *CTU*'s editorial advisory board, as well as from other family planning and women's health authorities. Mail your question to: Rebecca Bowers, Editor, *Contraceptive Technology Update,* 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Be sure to include information on how we can contact you. ■

Given the expense and poor predictive value of measuring FSH levels in this setting, I would instead arbitrarily continue the DMPA with supplemental estrogen until the patient is in her mid-50s. At that point, if desired, you can change the patient to conventional hormonal replacement therapy. The risk of ovulation / pregnancy is low in a woman in her mid-50s.

However, if this issue is of concern, to ensure "seamless" contraception in such a woman, I would encourage her to use barrier contraception for the first three to six months after discontinuing DMPA. If the woman did not appear to be heaving regular cycles off hormones [or on HRT], this would tend to confirm that menopause had indeed "arrived" and that the woman need not continue any contraception.

Nelson: This is not a conventional answer, but you may want to consider these ideas: It is really not clinically necessary to perfectly time the diagnosis of menopause in DMPA users. Cross-sectional studies show that long-term users of DMPA may have lower bone mineral density than controls. This bone mineralization loss apparently is reversed over time once a premenopausal woman stops using DMPA.

However, if a woman plans to use DMPA all the way up to menopause, it may be prudent to add physiologic estrogen replacement to the DMPA as the woman approaches the last few of her reproductive years to increase BMD. In this situation, with the woman using DMPA and estrogen, she can be continued on this treatment for a few years beyond the average age of menopause to ensure she does not need contraception. At that time, the DMPA can be transitioned to more conventional menopausal hormonal replacement.

Sharon Schnare, FNP, CNM, a Seattle-based family planning clinician and consultant: If a perimenopausal woman has symptoms of menopause on DMPA, then I would draw an FSH level. If the FSH is 30 or greater, I would consider her menopausal.

DMPA apparently blunts FSH to some degree. If I thought I needed a more accurate FSH, I could wait 12 weeks after her last DMPA shot, draw the FSH at that time.

I am not aware of any studies following FSH in older reproductive-age women on DMPA, so I do not know how long DMPA can blunt FSH after the last injection. It would also be reasonable to stop her DMPA injections at age 50 to 52 and start hormone replacement therapy at that time.

Wysocki: I would think a woman would have to be off DMPA or at the end of the 12 weeks at the very least, but there is also a refractory period of up to 11 to 18 months for return ovulation. If it was going to return, I certainly would not want her to go off contraception altogether. Perhaps you could transition her to oral contraceptives, if estrogen is not a problem, or mini-pills, if irregular bleeding isn't a problem, then go from there. ■

Congress delves into science with RU-486

By **Lisa Kaeser**, JD
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A high-profile amendment that would have banned final U.S. Food and Drug Administration (FDA) approval of a drug that causes early abortion, mifepristone, better known as RU-486, nearly made it into law this year. It was dropped at the last minute. If the amendment had been adopted, it would have represented the deepest congressional incursion into the FDA approval process on a specific drug to date.

In June, Rep. Tom Coburn (R-OK) offered an amendment to the fiscal year 1999 agriculture appropriations legislation (which funds the FDA,

among other agencies), stating, "None of the funds in this act may be used by the Food and Drug Administration for the testing, development, or approval (including approval of, production, manufacturing, or distribution) of any drug for the chemical inducement of abortion."

In a letter signed by 20 members, the amendment was called a "slap in the face of anyone who is fighting to beat cancer and other deadly diseases."

In his statement on the House floor, Rep. Coburn made his intent clear: to stop all further agency actions toward final approval of RU-486.

The saga of RU-486 has stretched on for more than a decade. It was introduced in France and is approved in two other countries, with others reportedly soon to follow. Discouraged by the U.S. political scene, the drug's original manufacturer gave the U.S. distribution rights to the nonprofit Population Council of New York City, which spearheaded the clinical trials in this country.

In 1996, the FDA issued an "approvable" letter, meaning that it had determined that the drug was safe and effective for the termination of early pregnancy. However, additional data on manufacturing practices and proposed labeling is necessary for final approval. While various obstacles — including the identification of a manufacturer — have delayed the process, the Coburn amendment would have stopped the process in its tracks.

Issue divides Congress

This year, Congress has been beset by reproductive health-related issues, largely at the behest of a small group of conservative members who have made them a top priority. In particular, the vote on so-called "partial birth" abortion was a difficult one for many members, especially in an election year when votes on social issues are closely scrutinized.

When the Coburn amendment was offered, anti-abortion members presented it as "another" abortion issue and stated they did not want their taxpayer dollars to fund abortion drugs.

Numerous medical, health, and research groups weighed in with three major arguments against the amendment:

• First, although abortions late in pregnancy are more difficult for many people to accept, RU-486 is an advance in that its use is in the earliest stages of a pregnancy. However, Congress was not dealing head on with the more fundamental question of whether abortion should be legal.

• Second, many groups questioned the propriety of Congress imposing its scientific judgment on the FDA.

• Third, the future implications of this action could be serious for a wide range of drugs and devices that might have an abortifacient effect but would be approved for other uses. This fight is led by Rep. Rosa DeLauro (D-CT), an ovarian cancer survivor. In a letter signed by 20 members, the amendment was called a "slap in the face of anyone who is fighting to beat cancer and other deadly diseases."

Amendment deleted, for now

Despite this vocal opposition, the House nonetheless approved the Coburn amendment by a vote of 223-202. The Senate, on the other hand, did not include similar language in its version of the agriculture appropriations bill, and it refused to accept the House version.

In the end, distracted by the presidential impeachment inquiry and the need to approve all appropriations measures before adjourning for the year, the Coburn amendment was deleted from the final version of the legislation. Still — particularly given the success in the House — the matter is likely to resurface next year, depending somewhat on shifts made in the makeup of Congress after the November elections.

FDA candidate quizzed

Notably, the agriculture bill was not the only forum for a debate on RU-486; its potential approval nearly submarined the nomination of Jane Henney as FDA commissioner.

A former FDA deputy and cancer researcher, Jane Henney was nominated by President Clinton to succeed David Kessler, a post that has been vacant since February 1997. During her confirmation process, she was grilled on numerous subjects, especially whether she would give final approval to RU-486.

Following her initial hearing by a Senate committee, Henney had to submit a lengthy response to additional questions from the senators. Her

answers focused on RU-486's approval "for its intended use," i.e. abortion, and its safety for a pregnant woman.

Although Henney's nomination has been approved by the committee and forwarded to the full Senate, the Senate did not take it up before leaving for the year. Consequently, it is highly likely that the RU-486 issue will crop up again early next year. Meanwhile, the FDA post will go unfilled. ■

CTUPDATES
News ■ Resources ■ Events

Mark these dates for March *CT* conferences

Usher in the new year by penciling in the dates for the annual *Contraceptive Technology* conferences. Get the latest information on issues and options in reproductive health care by attending one of the two events, both scheduled in March.

San Francisco and Washington, DC, are the 1999 sites, with the San Francisco session on March 11 to 13, followed by the Washington, DC, conference on March 25 to 27. Speakers will include nationally recognized clinicians and researchers, as well as the authors of *Contraceptive Technology*.

For additional information on the conferences, contact: Contemporary Forums, 11900 Silvergate Drive, Dublin, CA 94568-2257. Telephone: (925) 828-7100. Fax: (925) 828-2121. E-mail: hlth@cforums.com. Web: http://www.cforums.com. ▼

PATH launches World Wide Web site

Get summaries of reproductive health research findings and program information on key topics at Reproductive Health Outlook, a new World Wide Web site launched by the Program for Appropriate Technology (PATH).

A Seattle-based international nonprofit organization, PATH works to improve health, especially that of women and children. It developed the site primarily for reproductive health managers and decision makers in developing and transitional countries, but the information offers applications for established programs as well. The site is supported through a grant from the Redmond, WA-based William H. Gates Foundation.

Such topics as family planning, reproductive tract infections, sexual health, and cervical cancer are covered through research issues, project examples, and links to related Web sites and online journals.

The site also includes a community forum message boards where users can post reproductive health announcements or questions to colleagues worldwide.

To view the new site, go to the following Web address: http://www.rho.org. E-mail may be sent to this address: rho@path.org. Or write to Reproductive Health Outlook, PATH, 4 Nickerson St., Seattle, WA 98109. ■

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After reading this issue of *Contraceptive Technology Update,* the continuing education participant should be able to:

- State what action by the U.S. Food and Drug Administration resulted in more brand-specific requests for oral contraceptives.
- Cite the major finding of pooled results from two West Coast institutions in regard to use of low-dose oral contraceptives.
- State the significance of counseling on use of condoms following sterilization.
- Name two medical technology advances that have allowed safe, effective use of early surgical abortion. ■

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