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# JOURNAL

MARCH 2000

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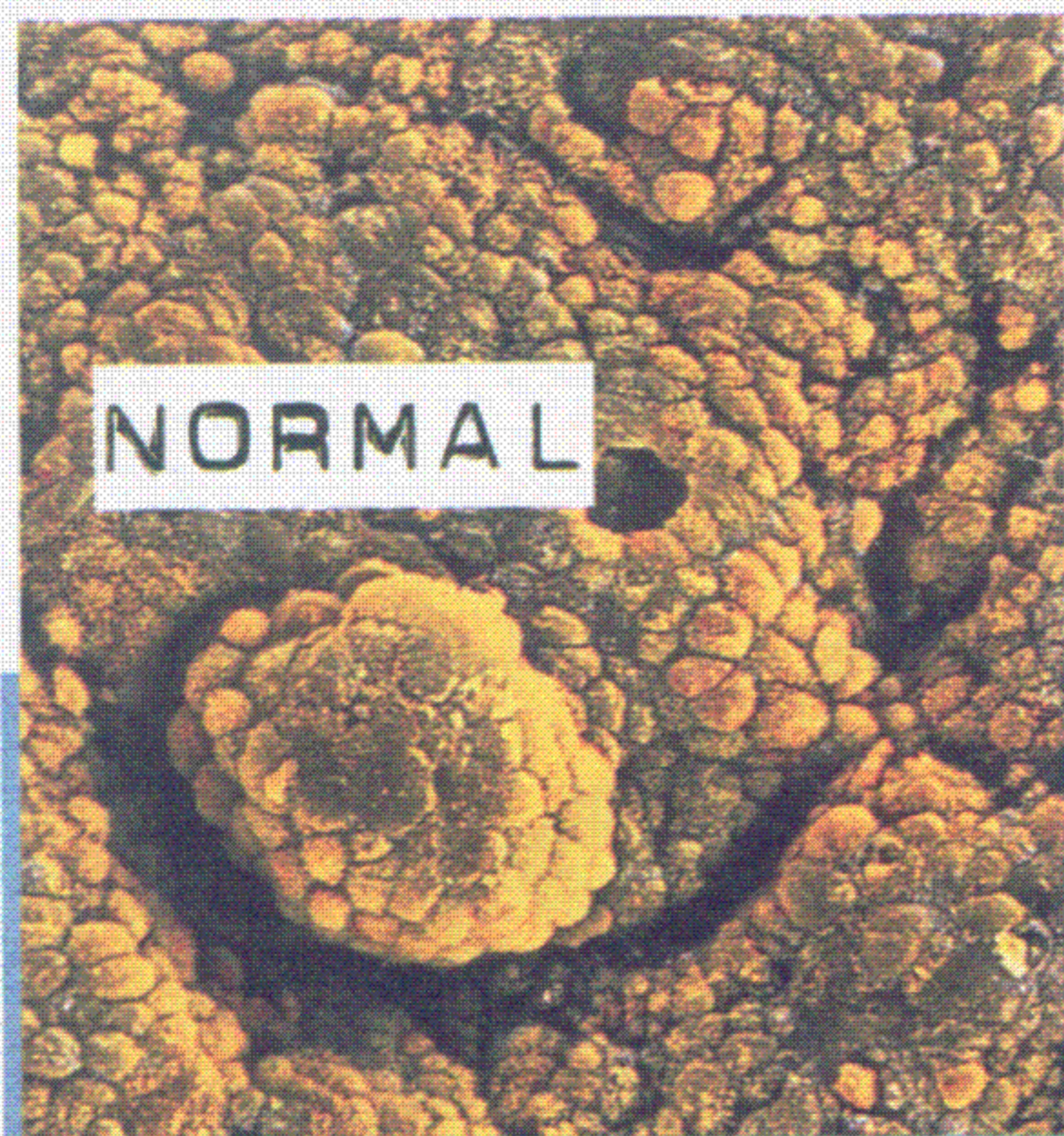
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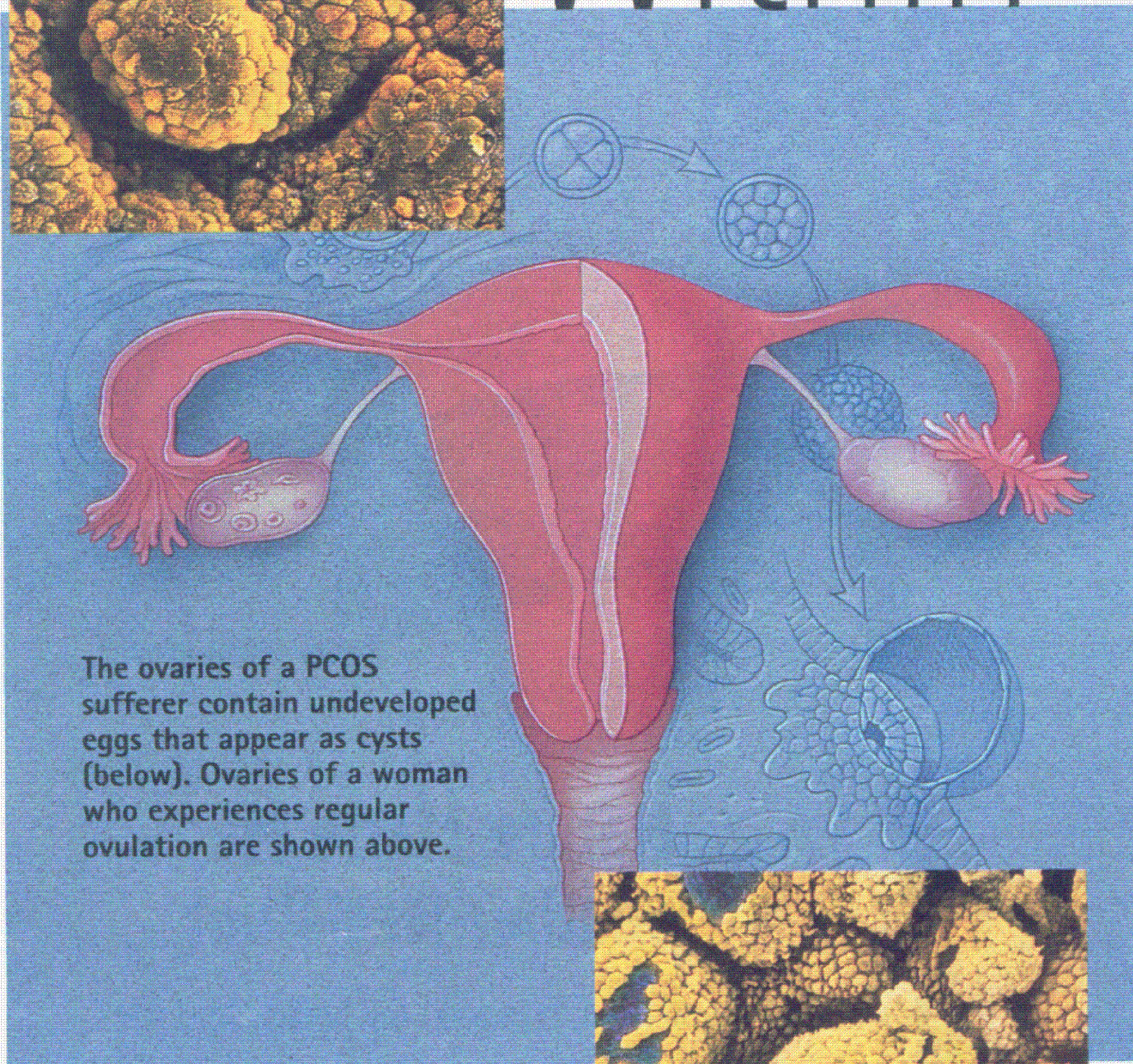




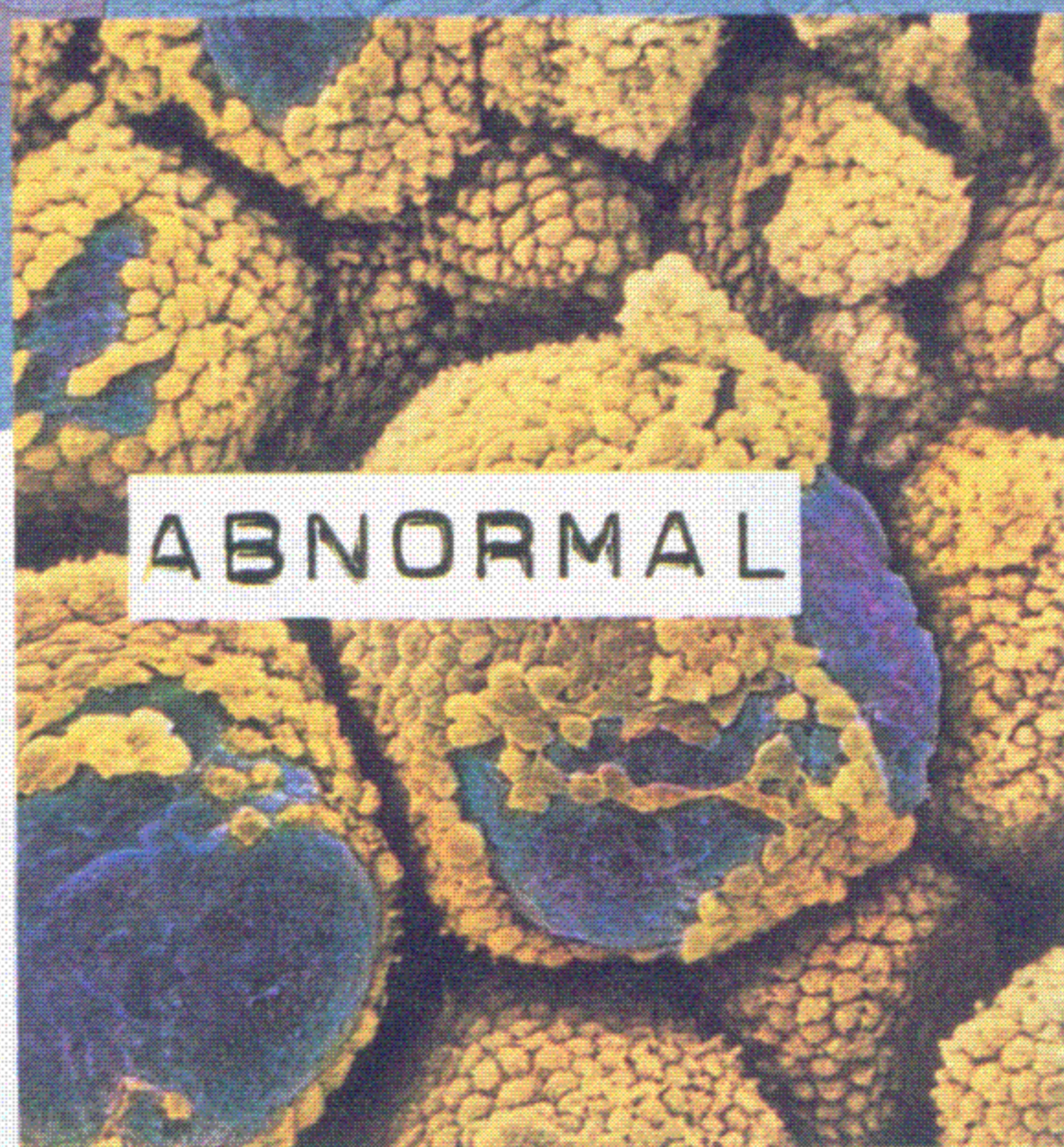
# The **DANGER** Within



**NORMAL**



The ovaries of a PCOS sufferer contain undeveloped eggs that appear as cysts (below). Ovaries of a woman who experiences regular ovulation are shown above.



**ABNORMAL**

Beth Kushnick's problem began during puberty. Her friends got their periods; she didn't. During her late teens, her weight shot up by forty pounds. When she finally began to menstruate, her periods were long and heavy; then she'd go for six months at a stretch without one. Her twenties were just as bad: She was plagued by constant fatigue and tender and bloated ovaries.

Kushnick, now thirty-nine and working in the film industry in New York, knew something was wrong. But visits to two gynecologists and two endocrinologists provided no answers. "Basically," she says, "I was put on the Pill to regulate my periods and sent on my way."

Frustrated, Kushnick took action, contacting women's health organiza-

tions and combing medical libraries for clues. She finally deduced she was suffering from Polycystic Ovary Syndrome (PCOS), a hormonal and metabolic condition. After five years of searching, she discovered the National Organization for Rare Disorders, in New Fairfield, Connecticut, which put her in contact with other women who shared similar symptoms. "What a relief it was to find out I wasn't alone," says Kushnick.

It's the leading cause of female infertility. As many as five million U.S. women have it. Could you be at risk for Polycystic Ovary Syndrome?

By Kathleen McAuliffe

Though many women have never heard of it, PCOS affects as many as five million women in the United States (or one in ten), and is the leading cause of female infertility. It is, says Kushnick, "absurdly out of place on a list of rare disorders." Left untreated, it can cause life-threatening complications.

PCOS was first recognized more than sixty years ago (and initially was called Stein-Leventhal syndrome after the two doctors who discovered it). But it is a complicated condition frequently overlooked by physicians. Generic symptoms are part of the problem. Erratic periods, acne, hirsutism (excess hair on the face and body), and balding on the crown of the head—caused by elevated levels of male hormones—are common. Sixty percent of women with PCOS are overweight. All of these symptoms, however, can be caused by other disorders.

And to complicate matters, not all cases look alike: One woman's symptoms may scream PCOS—obesity, raging acne, heavy facial hair. Another patient—a woman of normal weight whose only complaint is a longer-than-normal menstrual cycle—may be more difficult to diagnose. Even the symptom that gives the disorder its modern *(continued)*

PHOTOS, FROM TOP: PROF. P. MOTTA/CUSTOM MEDICAL STOCK PHOTO, MARCIA HARTSOCK/STOCK SHOP/MEDICHOME, PROFS. P. M. MOTTA AND S. MAKABE/CUSTOM MEDICAL STOCK PHOTO.



# BuSpar® (buspirone HCl, USP)

Rx only

Brief Summary of Prescribing Information. For complete prescribing information, please consult official package circular.

**CONTRAINDICATIONS:** Hypersensitivity to buspirone hydrochloride.

**WARNINGS:** The administration of BuSpar to a patient taking a monoamine oxidase inhibitor (MAOI) may pose a hazard. Since blood pressure has become elevated when BuSpar was administered concomitantly with an MAOI, such concomitant use is not recommended. BuSpar should not be employed in lieu of appropriate antipsychotic treatment.

**PRECAUTIONS: General - Interference with Cognitive and Motor Performance:** Although buspirone is less sedating than other anxiolytics and does not produce significant functional impairment, its CNS effects in a given patient may not be predictable; therefore, patients should be cautioned about operating an automobile or using complex machinery until they are reasonably certain that buspirone does not affect them adversely. Although buspirone has not been shown to increase alcohol-induced impairment in motor and mental performance, it is prudent to avoid concomitant use with alcohol. **Potential for Withdrawal Reactions in Sedative/Hypnotic/Anxiolytic Drug-Dependent Patients:** Because buspirone will not block the withdrawal syndrome often seen with cessation of therapy with benzodiazepines and other common sedative/hypnotic drugs, before starting buspirone withdraw patients gradually from their prior treatment, especially those who used a CNS depressant chronically. Rebound or withdrawal symptoms may occur over varying time periods, depending in part on the type of drug, and its elimination half-life. The withdrawal syndrome can appear as any combination of irritability, anxiety, agitation, insomnia, tremor, abdominal cramps, muscle cramps, vomiting, sweating, flu-like symptoms without fever, and occasionally, even as seizures. **Possible Concerns Related to Buspirone's Binding to Dopamine Receptors:** Because buspirone can bind to central dopamine receptors, a question has been raised about its potential to cause acute and chronic changes in dopamine mediated neurological function (e.g., dystonia, pseudoparkinsonism, akathisia, and tardive dyskinesia). Clinical experience in controlled trials has failed to identify any significant neuroleptic-like activity; however, a syndrome of restlessness, appearing shortly after initiation of treatment, has been reported: the syndrome may be due to increased central noradrenergic activity or may be attributable to dopaminergic effects (i.e., represent akathisia).

**Information for Patients - Patients** should be instructed to inform their physician about any medications, prescription or nonprescription, alcohol, or drugs they are now taking or plan to take during treatment with buspirone; to inform their physician if they are pregnant, are planning to become pregnant, or become pregnant while taking buspirone; to inform their physician if they are breast feeding; and not to drive a car or operate potentially dangerous machinery until they experience how medication affects them. **Drug Interactions (See WARNINGS) - Trazodone:** One report suggests that the concomitant use of Desyrel® (trazodone hydrochloride) and BuSpar may have caused 3- to 6-fold elevations on SGPT (ALT). **Haloperidol:** In normal volunteers, concomitant administration of BuSpar and haloperidol resulted in increased serum haloperidol concentrations. The clinical significance of this finding is not clear. **Amitriptyline:** After addition of buspirone to the amitriptyline dose regimen, no statistically significant differences in the steady-state pharmacokinetic parameters ( $C_{max}$ , AUC, and  $C_{min}$ ) of amitriptyline or its metabolite nortriptyline were observed. **Diazepam:** After addition of buspirone to the diazepam dose regimen, no statistically significant differences in the steady-state pharmacokinetic parameters ( $C_{max}$ , AUC, and  $C_{min}$ ) were observed for diazepam, but increases of about 15% were seen for nordiazepam, and minor adverse clinical effects (dizziness, headache, and nausea) were observed. **Triazolam/Flurazepam:** Coadministration of buspirone with either triazolam or flurazepam did not appear to prolong or intensify the sedative effects of either benzodiazepine. **Nefazodone:** In a study of steady-state pharmacokinetics in healthy volunteers, coadministration of buspirone (2.5 or 5 mg b.i.d.) with nefazodone (250 mg b.i.d.) resulted in marked increases in plasma buspirone concentrations (increases up to 20-fold in  $C_{max}$  and up to 50-fold in AUC) and statistically significant decreases (-50%) in plasma concentrations of the buspirone metabolite 1-PP. With 5 mg b.i.d. doses of buspirone, slight increases in AUC were observed for nefazodone (23%) and its metabolites hydroxynefazodone (17%) and meta-chlorophenylpiperazine (9%). Subjects receiving buspirone 5 mg b.i.d. and nefazodone 250 mg b.i.d. experienced side effects such as lightheadedness, asthenia, dizziness, and somnolence. If the two drugs are to be used in combination, a low dose of buspirone (e.g., 2.5 mg b.i.d.) is recommended. Subsequent dose adjustment of either drug should be based on clinical assessment.

**Other Psychotropics:** The concomitant use of BuSpar with other CNS-active drugs should be approached with caution. **Cimetidine:** Coadministration of buspirone with cimetidine was found to increase  $C_{max}$  (40%) and  $T_{max}$  (2-fold), but had minimal effects on the AUC of buspirone. **Erythromycin:** In a study in healthy volunteers, coadministration of BuSpar (10 mg/day) with erythromycin (1.5 g/day) increased plasma buspirone concentrations (fivefold increase in  $C_{max}$  and sixfold increase in AUC). These pharmacokinetic interactions were accompanied by an increased incidence of side effects attributable to buspirone. If the two drugs are to be used in combination, a low dose of buspirone (e.g., 2.5 mg b.i.d.) is recommended. Subsequent dose adjustment of either drug should be based on clinical assessment. **Itraconazole:** In healthy volunteers, coadministration of BuSpar (10 mg/day) with itraconazole (200 mg/day) increased plasma buspirone concentrations (13-fold increase in  $C_{max}$  and 19-fold increase in AUC). These pharmacokinetic interactions were accompanied by an increased incidence of side effects attributable to buspirone. If the two drugs are to be used in combination, a low dose of buspirone (e.g., 2.5 mg b.i.d.) is recommended. Subsequent dose adjustment of either drug should be based on clinical assessment. **Potential Interaction with Drugs That Inhibit Cytochrome P450 3A4 (CYP3A4):** Buspirone has been shown *in vitro* to be metabolized by CYP3A4. Consequently, if BuSpar is to be used in combination with a potent inhibitor of CYP3A4, a low dose of buspirone (e.g., 2.5 mg b.i.d.) is recommended. Subsequent dose adjustment of either drug should be based on clinical assessment. **Protein Binding:** *In vitro*, buspirone does not displace tightly bound drugs like phenytoin, propranolol, and warfarin from serum proteins but may displace less firmly bound drugs like digoxin. However, there was one report of prolonged prothrombin time when buspirone was given to a patient also treated with warfarin, phenytoin, phenobarbital, digoxin and Synthroid®. Therapeutic levels of aspirin, desipramine, diazepam, flurazepam, ibuprofen, propranolol, thioridazine, and tolbutamide had only a limited effect on the extent of binding of buspirone to plasma proteins (see **CLINICAL PHARMACOLOGY** section).

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** No evidence of carcinogenic potential was observed in rats or mice; buspirone did not induce point mutations, nor was DNA damage observed; chromosomal aberrations or abnormalities did not occur. **Pregnancy: Teratogenic Effects:** Pregnancy Category B: Should be used during pregnancy only if clearly needed. **Nursing Mothers:** Administration to nursing women should be avoided if clinically possible. **Pediatric Use:** The safety and effectiveness have not been determined in individuals below 18 years of age. **Use in the Elderly:** The safety and efficacy profiles of buspirone in 605 anxious, elderly patients (mean age = 70.8 years) were similar to those in a younger population (mean age = 43.3 years). There were no effects of age on the pharmacokinetics of buspirone. **Use in Patients With Impaired Hepatic or Renal Function:** Since buspirone is metabolized by the liver and excreted by the kidneys, it is not recommended in severe hepatic or renal impairment. A pharmacokinetic study in patients with impaired hepatic or renal function demonstrated increased plasma levels and a lengthened half-life of buspirone (see **CLINICAL PHARMACOLOGY** section).

**ADVERSE REACTIONS (See also PRECAUTIONS): Commonly Observed:** The more commonly observed untoward events, not seen in an equivalent incidence in placebo-treated patients include dizziness, nausea, headache, nervousness, lightheadedness, and excitement. **Associated With Discontinuation of Treatment:** The more common events causing discontinuation included: central nervous system disturbances (3.4%), primarily dizziness, insomnia, nervousness, drowsiness, lightheaded feeling; gastrointestinal disturbances (1.2%), primarily nausea; miscellaneous disturbances (1.1%), primarily headache and fatigue. In addition, 3.4% of patients had multiple complaints, none of which could be characterized as primary. **Incidence in Controlled Clinical Trials:** Adverse events reported by 1% or more of 477 patients who received buspirone in four-week, controlled trials: **Cardiovascular:** Tachycardia/palpitations 1%, CNS: Dizziness 12%, drowsiness 10%, nervousness 5%, insomnia 3%, lightheadedness 3%, decreased concentration 2%, excitement 2%, anger/hostility 2%, confusion 2%, depression 2%. **EENT:** Blurred vision 2%. **Gastrointestinal:** Nausea 8%, dry mouth 3%, abdominal/gastric distress 2%, diarrhea 2%, constipation 1%, vomiting 1%. **Musculoskeletal:** Musculoskeletal aches/pains 1%. **Neurological:** Numbness 2%, paresthesia 1%, incoordination 1%, tremor 1%. **Skin:** Skin rash 1%. **Miscellaneous:** Headache 6%, fatigue 4%, weakness 2%, sweating/clamminess 1%. **Other Events Observed During the Entire Premarketing Evaluation:** The relative frequency of all other undesirable events reasonably associated with the use of buspirone in approximately 3000 subjects who took multiple doses under well-controlled, open and uncontrolled conditions is defined as follows: Frequent are those occurring in at least 1/100 patients; infrequent are those occurring in 1/100 to 1/1000 patients; and rare are those occurring in less than 1/1000 patients. **Cardiovascular:** frequent: non-specific chest pain; infrequent: syncope, hypotension, and hypertension; rare: cerebrovascular accident, congestive heart failure, myocardial infarction, cardiomyopathy, bradycardia. **Central Nervous System:** frequent: dream disturbances; infrequent: depersonalization, dysphoria, noise intolerance, euphoria, akathisia, tearfulness, loss of interest, dissociative reaction, hallucinations, involuntary movements, slowed reaction time, suicidal ideation, seizures; rare: feelings of claustrophobia, cold intolerance, stupor, slurred speech, psychosis. **EENT:** frequent: tinnitus, sore throat, nasal congestion; infrequent: redness and itching of the eyes, altered taste, altered smell, conjunctivitis; rare: inner ear abnormality, eye pain, photophobia, pressure on eyes. **Endocrine:** rare: galactorrhea, thyroid abnormality. **Gastrointestinal:** infrequent: flatulence, anorexia, increased appetite, salivation, irritable colon, rectal bleeding; rare: burning of the tongue. **Genitourinary:** infrequent: urinary frequency, urinary hesitancy, menstrual irregularity and spotting, dysuria; rare: amenorrhea, pelvic inflammatory disease, enuresis, nocturia. **Musculoskeletal:** infrequent: muscle cramps, muscle spasms, rigid/stiff muscles, arthralgias; rare: muscle weakness. **Respiratory:** infrequent: hyperventilation, shortness of breath, and chest congestion; rare: epistaxis. **Sexual Function:** infrequent: decreased or increased libido; rare: delayed ejaculation, impotence. **Skin:** infrequent: edema, pruritus, flushing, easy bruising, hair loss, dry skin, facial edema, blisters; rare: acne, thinning of nails. **Clinical Laboratory:** infrequent: increases in hepatic aminotransferases (SGOT, SGPT); rare: eosinophilia, leukopenia, thrombocytopenia. **Miscellaneous:** infrequent: weight gain, fever, roaring sensation in the head, weight loss, malaise; rare: alcohol abuse, bleeding disturbance, loss of voice, and hiccoughs.

**POSTINTRODUCTION CLINICAL EXPERIENCE:** Rare occurrences of allergic reactions (including urticaria), angioedema, cogwheel rigidity, dizziness (rarely reported as vertigo), dystonic reactions, ataxias, extrapyramidal symptoms, dyskinesias (acute and tardive), ecchymosis, emotional lability, serotonin syndrome, transient difficulty with recall, urinary retention and visual changes (including tunnel vision) have been reported. Because of the uncontrolled nature of these spontaneous reports, a causal relationship to BuSpar (buspirone HCl) has not been determined.

**DRUG ABUSE AND DEPENDENCE: Controlled Substance Class:** Not a controlled substance. **Physical and Psychological Dependence:** Buspirone has shown no potential for abuse or diversion and there is no evidence that it causes tolerance, or either physical or psychological dependence. However, since it is difficult to predict from experiments the extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of buspirone misuse or abuse (e.g., development of tolerance, incrementation of dose, drug-seeking behavior).

**OVERDOSAGE: Signs and Symptoms:** At doses approaching 375 mg/day the following symptoms were observed: nausea, vomiting, dizziness, drowsiness, miosis, and gastric distress. A few cases of overdosage have been reported with complete recovery as the usual outcome. No deaths have been reported following overdosage with BuSpar alone. Rare cases of intentional overdosage with a fatal outcome were invariably associated with ingestion of multiple drugs and/or alcohol, and causal relationship to buspirone could not be determined. **Recommended Overdose Treatment:** General symptomatic and supportive measures should be used along with immediate gastric lavage. No specific antidote is known and dialyzability of buspirone has not been determined.

U.S.A. Patent Nos. 3,717,634 and 4,182,763

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Revised April 1999

## THE DANGER WITHIN

Continued

name—undeveloped eggs in the ovaries that appear as multiple cysts in ultrasound images—doesn't affect every woman with PCOS.

"In my experience, as many as half of women walking around with PCOS don't know it," says Roger A. Lobo, M.D., chairman of the department of obstetrics and gynecology at Columbia University College of Physicians and Surgeons, in New York City.

Sometimes a patient with PCOS is diagnosed in her teens—perhaps by a gynecologist who's able to piece together disparate symptoms, or by a dermatologist who's "particularly aware of what male hormones can do to the skin," explains Walter Futterweit, M.D., a clinical professor of medicine in the division of endocrinology at Mount Sinai School of Medicine, in New York City. Other women don't discover they have PCOS until they have trouble conceiving a child.

But new research suggests that PCOS is much more than just a fertility problem. Scientists have discovered that women with the disorder are unable to use insulin efficiently. "PCOS is a metabolic disturbance with far-ranging health effects, increasing a woman's risk of diabetes, heart disease and endometrial cancer," says John Nestler, M.D., professor of medicine and chairman of the division of endocrinology and metabolism at Virginia Commonwealth University, in Richmond.

Fortunately, once diagnosed, the disorder can be controlled. Mild cases can be managed with appropriate diet and exercise to help correct the metabolic problem at its root. Drugs have proved effective in helping to regulate the menstrual cycle, counter excess hair growth, even to restore fertility.

Being informed is the key. There are more resources for the disorder now than when Kushnick was looking twelve years ago—thanks, in part, to a growing network of PCOS women. "I started chatting with them over the phone, and followed up with packets of medical literature I'd



collected about PCOS," says Kushnick. Soon she was overwhelmed with requests.

Today, she heads the PCOS support group of the American Infertility Association, a nonprofit organization based in New York. Last October, she chaired a conference to educate patients on PCOS at Mount Sinai.

Doctors need to be informed, too. "Traditionally, reproductive disorders have not been part of general medical training," says Andrea Dunaif, M.D., an internist endocrinologist specializing in reproduction at Brigham and Women's Hospital, in Boston. "A lot of obstetricians, gynecologists and internists tell PCOS women they're too fat, put them on the Pill, and that's it. There's often a lack of appreciation of the long-term consequences."

### ARE YOU AT RISK?

Though the underlying cause of PCOS remains a mystery, medical researchers believe that insulin resistance sets off a chain reaction that throws hormones out of kilter. As the disorder progresses, certain cells in the body grow less responsive to insulin and blood-sugar levels climb, which causes the pancreas to step up insulin production. In turn, the excess insulin stimulates the ovaries and adrenal gland to churn out testosterone and other androgens, which can disrupt ovulation. Depending on a woman's sensitivity to male hormones, she may develop acne and male-pattern hair growth or loss. Failure to properly utilize insulin also can slow metabolism, which helps explain why so many PCOS women are overweight, says Dunaif. At the same time, she notes, it's likely the male

hormones increase appetite.

But that's not the worst of it. A PCOS woman continues to produce estrogen, but stops manufacturing progesterone. This imbalance causes the lining of the uterus to continue thickening, a condition that can invite endometrial cancer. Estrogen also stimulates the pituitary gland to release luteinizing hormone (LH), which signals the ovaries to release an egg. In normal functioning, after the egg is released, levels of LH drop; in women with PCOS, they remain elevated.

PCOS can culminate in diabetes and cardiovascular disease. Women with the disorder tend to have low HDLs (good cholesterol), high LDLs (bad cholesterol) and elevated triglycerides—factors that make them prime candidates for heart attack and stroke.

Experts advise any woman with an irregular menstrual cycle to be evaluated for PCOS. Family history of the disease is also a risk factor. In a study of around one hundred families, Dunaif found that 50 percent of sisters of PCOS women either have the disorder or show signs of it.

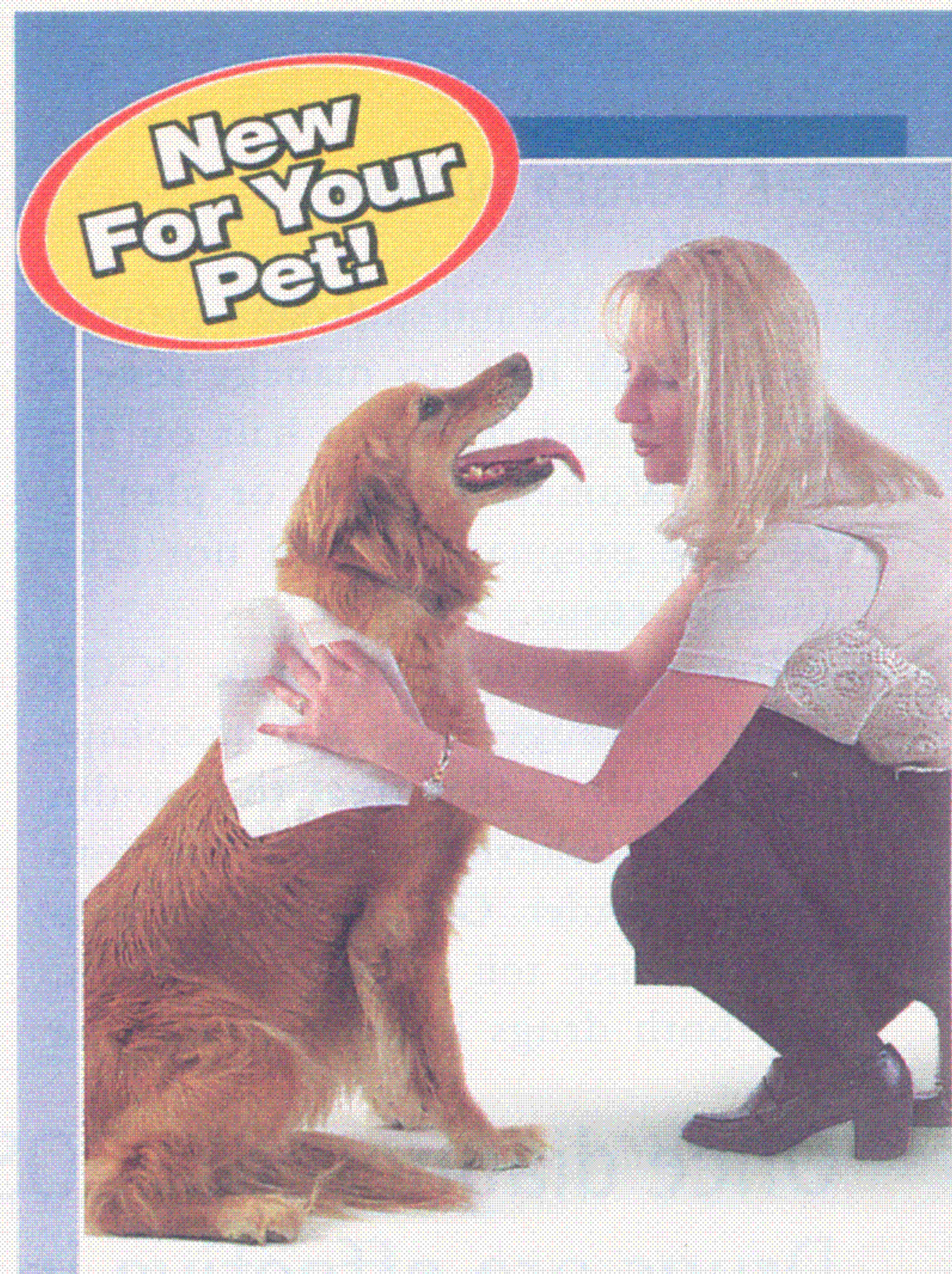
### A DIFFICULT BALANCING ACT

Because the range and severity of symptoms vary enormously, no treatment fits all patients. If the woman is overweight, doctors first recommend lifestyle changes—regular exercise and a low-calorie, low-carbohydrate diet. Slimming down can help restore fertility and lower male hormone levels for some patients, experts say.

Long a mainstay of PCOS therapy, oral contraceptives are still used to regulate periods and suppress excess male hormones, which can clear acne and alleviate hirsutism. More important, they reduce the risk of endometrial cancer. (Women with PCOS should avoid forms of the Pill that contain a progestin called Levonorgestrel, which mimics male hormones, potentially worsening symptoms.) Spironolactone is commonly prescribed with (continued)

### FOR MORE INFORMATION

To learn more about Polycystic Ovary Syndrome, contact the American Infertility Association, 666 Fifth Avenue, Suite 278, New York, NY 10103; 888-917-3777; [www.americaninfertility.org](http://www.americaninfertility.org)



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## THE DANGER WITHIN

Continued

the Pill for its anti-androgen properties, which help to manage severe hirsutism and replenish hair on the head. (Women who are or plan to become pregnant should not take spironolactone.)

But the latest approach to PCOS therapy is drugs—such as Glucophage and Rezulin—that treat the insulin resistance believed to be at the core of the disorder. Glucophage can help patients lose ten to fifteen pounds, and both drugs lower testosterone

off. After three rounds of Clomid and four rounds with gonadotropin, her pregnancy was complication-free, and she now has a healthy two-year-old girl. Her success story is not unique: The vast majority of PCOS women can have a baby with fertility therapy.

The latest development is an experimental drug, INS-1, an insulin-sensitizing agent similar to Glucophage and Rezulin, that has shown promising results in clinical trials. After six to eight weeks on the drug, 86 percent of PCOS patients ovulated, compared with 27 percent of women in the

## Once diagnosed, PCOS can be controlled. Drugs are effective in helping to regulate the menstrual cycle and restore fertility

levels, which decreases acne and hirsutism. The medications have also been shown to reduce circulating levels of LH and insulin—changes that experts hope may translate into increased protection against diabetes and heart disease.

Finally, Glucophage and Rezulin frequently restore ovulation. In clinical trials of Glucophage, PCOS women who'd been unable to conceive by any other method got pregnant.

Another approach for PCOS sufferers unable to conceive is the fertility drug clomiphene citrate (Clomid, Milophene or Serophene). If three cycles of the medication fail to induce ovulation, the next step is injections of gonadotropin, which are pituitary hormones that regulate ovulation.

Because those with PCOS may be at higher risk than others for complications of fertility treatments—multiple births, miscarriage and ovarian hyperstimulation, a potentially life-threatening condition—they should choose fertility specialists with expertise in treating these conditions.

“My doctor was very conservative, stepping up the dose of the fertility drugs in tiny increments to avoid serious side effects,” says a thirty-five-year-old PCOS patient who requested anonymity. The cautious approach paid

placebo group, according to a study reported last April in *The New England Journal of Medicine*. And no side effects were reported.

### LIVING WITH PCOS

Even with treatment, having PCOS can be an ordeal. The most distressing aspect, according to a survey of patients, is the disorder's visible markers, which can be especially devastating for young women.

“Freakish” is how a thirty-nine-year-old Sacramento-based journalism student describes her early twenties, when PCOS threw her a quadruple whammy: Her weight ballooned, and she developed acne, facial hair and bald patches on the crown of her head.

Lacking medical insurance, she went to the California Department of Health Services, which refused to cover electrolysis. She was able to get another state agency to cover four hundred hours of facial electrolysis, and she no longer endures the indignity of a beard.

For now, PCOS's effects aren't easily erased, but most sufferers agree that education and emotional support can help. “The feeling of solidarity is so empowering,” says Kushnick. ■

*Kathleen McAuliffe is a frequent contributor to Ladies' Home Journal.*

## Transderm Scop® scopolamine 1.5 mg

Transdermal Therapeutic System

Programmed to deliver *in vivo* approximately 1.0 mg of scopolamine over 3 days

Brief Summary  
(For full prescribing information, see package insert)

**INDICATIONS AND USAGE:** Transderm Scop is indicated for prevention of nausea and vomiting associated with motion sickness in adults. The patch should be applied only to skin in the postauricular area.

**CONTRAINDICATIONS:** Transderm Scop is specifically contraindicated in persons who are hypersensitive to the drug scopolamine or to other belladonna alkaloids, or to any ingredient or component in the formulation or delivery system, or in patients with angle-closure (narrow angle) glaucoma.

**WARNINGS:** Transderm Scop should not be used in children and should be used with special caution in the elderly. See PRECAUTIONS.

Since drowsiness, disorientation, and confusion may occur with the use of scopolamine, patients should be warned of the possibility and cautioned against engaging in activities that require mental alertness, such as driving a motor vehicle or operating dangerous machinery.

Potentially alarming idiosyncratic reactions may occur with ordinary therapeutic doses of scopolamine.

### PRECAUTIONS

**General:** Scopolamine should be used with caution in patients with pyloric obstruction, or urinary bladder neck obstruction. Caution should be exercised when administering an antiemetic or antimuscarinic drug to patients suspected of having intestinal obstruction.

Transderm Scop should be used with special caution in the elderly or in individuals with impaired metabolic, liver, or kidney functions, because of the increased likelihood of CNS effects.

Caution should be exercised in patients with a history of seizure or psychosis, since scopolamine can potentially aggravate both disorders.

**Information for Patients:** Since scopolamine can cause temporary dilation of the pupils and blurred vision if it comes in contact with the eyes, patients should be strongly advised to wash their hands thoroughly with soap and water immediately after handling the patch. In addition, it is important that used patches be disposed of properly to avoid contact with children or pets.

Patients should be advised to remove the patch immediately and contact a physician in the unlikely event that they experience symptoms of acute narrow-angle glaucoma (pain in and reddening of the eyes accompanied by dilated pupils). Patients should also be instructed to remove the patch if they develop any difficulties in urinating.

Patients should be warned against driving a motor vehicle or operating dangerous machinery while wearing the patch. Patients who engage in these activities should also be aware of the possibility of withdrawal symptoms when the patch is removed. Patients who expect to participate in underwater sports should be cautioned regarding the potentially disorienting effects of scopolamine. A patient brochure is available.

**Drug Interactions:** Scopolamine should be used with care in patients taking drugs, including alcohol, capable of causing CNS effects. Special attention should be given to drugs having anticholinergic properties, e.g., belladonna alkaloids, antihistamines (including meclizine), and anti-depressants.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** No long-term studies in animals have been performed to evaluate carcinogenic potential. Fertility studies were performed in female rats and revealed no evidence of impaired fertility or harm to the fetus due to scopolamine hydrobromide administered by daily subcutaneous injection. In the highest-dose group (plasma level approximately 500 times the level achieved in humans using a transdermal system), reduced maternal body weights were observed.

**Pregnancy Category C:** Teratogenic studies were performed in pregnant rats and rabbits with scopolamine hydrobromide administered by daily intravenous injection. No adverse effects were recorded in the rats. In the rabbits, the highest dose (plasma level approximately 100 times the level achieved in humans using a transdermal system) of drug administered had a marginal embryotoxic effect. Transderm Scop should be used during pregnancy only if the anticipated benefit justifies the potential risk to the fetus.

**Nursing Mothers:** It is not known whether scopolamine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Transderm Scop is administered to a nursing woman.

**Pediatric Use:** Children are particularly susceptible to the side effects of belladonna alkaloids. Transderm Scop should not be used in children because it is not known whether this system will release an amount of scopolamine that could produce serious adverse effects in children.

**ADVERSE REACTIONS:** The most frequent adverse reaction to Transderm Scop is dryness of the mouth. This occurs in about two thirds of the people. A less frequent adverse reaction is drowsiness, which occurs in less than one sixth of the people. Transient impairment of eye accommodation, including blurred vision and dilation of the pupils, is also observed.

The following adverse reactions have also been reported on infrequent occasions during the use of Transderm Scop: disorientation; memory disturbances; dizziness; restlessness; hallucinations; confusion; difficulty urinating; rashes and erythema; acute narrow-angle glaucoma; and dry, itchy, or red eyes.

**Drug Withdrawal:** Symptoms including dizziness, nausea, vomiting, headache, and disturbances of equilibrium have been reported in a few patients following discontinuation of the use of the Transderm Scop system. These symptoms have occurred most often in patients who have used the system for more than three days.

**OVERDOSAGE:** Overdosage with scopolamine may cause disorientation, memory disturbances, dizziness, restlessness, hallucinations, confusion, psychosis, convulsions, bronchospasm and respiratory depression, and muscular weakness. Should these symptoms occur, the Transderm Scop patch should be removed immediately, adequate hydration should be maintained, and appropriate symptomatic treatment initiated.

**CAUTION:** Federal law prohibits dispensing without prescription.

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