

P.O. Box 982

Evanston, Illinois 60204

IN THIS ISSUE:

Endometriosis ... Fertility Drugs ... The Tylenol Tragedy



**Dr. Robert
Mendelsohn**

This issue of my Newsletter covers three diverse subjects--Endometriosis, Fertility Drugs, and the Tylenol Tragedy. The first two subjects appear because you readers have expressed interest in them. The third subject is as important in its long-term implications as it is in terms of a short-term disaster.

Appearing in the same historical timeframe as the epidemic of infertility is today's epidemic of endometriosis. Endometriosis occurred so infrequently in the past that, when I was a medical student at the University of Chicago, the appearance of a case of endometriosis was sufficient to call the entire class to see the patient. Today, almost every woman knows someone who has endometriosis.

While modern gynecology seems largely to have solved the problem of unwanted pregnancy (at least to the satisfaction of physicians), it now tries to cope with the new epidemic (as high as 25 percent) of infertility. Powerful treatments are being recommended in an atmosphere of almost total absence of controlled scientific statistically valid studies. The ob-gyn's reports are anecdotal: "I treated X number of infertile couples, and X + 2 females got pregnant." Since the doctor's treatment is both unscientific and unproven, you, the patient, stand at great risk unless you have the same information available to you as does the doctor. Hence, this issue of the Newsletter.

The reason for including Tylenol in this Newsletter is because of my prediction that the focus of public attention on this tragedy and the resulting revelations about the drug industry's manufacturing processes will have major implications for the future of both non-prescription and prescription drugs, as well as medical practice in our country.

Q

I am 27 years old and am suffering from endometriosis. Surprisingly, I know quite a few women with the same problem. Can you discuss some symptoms, causes, and cures for this condition?--Mrs. M.F.

A

*Explaining
endometriosis*

Endometriosis is as obscure as its name: "Endo" means inside, "metrium" uterus, and "osis" an increase. The word refers to an infiltration of the kind of tissue normally found only in the inner lining of the uterus into the muscular part of the uterus and elsewhere.

While no one really knows its cause, it is more common in women who have never been pregnant, and pregnancy usually relieves the condition.

Since the U.S. now has a very low birth rate, I am not surprised that you are encountering women with the same problem, and I would expect to see a continuing increase in endometriosis and other diseases that occur in childless women.

A variety of drugs and surgical procedures are used to relieve the pain, bleeding, and other symptoms of this condition, but there are risks associated with treatment--one of which is permanent infertility.

Q My 17-year-old daughter began menstruating when she was 14. She had no difficulties until about seven months ago when she began experiencing severe menstrual cramps prior to the onset of her period. These cramps usually last from three to four days. When I spoke to my physician about it, he suggested she do certain exercises. She followed that advice but felt no relief. We then consulted my gynecologist who said her condition sounded like endometriosis. After an examination, he told me he was sure of his diagnosis, and he prescribed birth control pills. When I told him that I had doubts about the Pill because of the adverse publicity it has received, he replied that this was the only way to treat my daughter, other than with surgery.

Three months have gone by, and my daughter now experiences severe nausea upon wakening, as well as having feelings of nervousness and irritability. Some days she feels well, but there are more days when she doesn't. This all began when she started taking the Pill. She now also has a breast condition that has been explained as growth tissue, but I don't want the Pill to trigger something of a more severe nature.

Should I take her for another opinion? Is endometriosis common in such a young girl? Is there a specific test to determine this condition? Will she be able to have children one day if this condition is treated?

I am very concerned about my daughter's continued use of the Pill. She was always a healthy child. The only out-of-the-ordinary incident I can recall occurred at age 9, when she experienced severe stomach pain just below the navel and toward her right side. At that time, the doctors I consulted said it might have something to do with the system readying itself for ovulation.

I would appreciate any advice you can offer.--S.P.

A

*The Pill
prescribed
for teen's
endometriosis*

Endometriosis can range in extent from very mild to quite severe; accordingly, treatment can range from aspirin through hormones all the way to surgery. The condition can disappear with pregnancy or as mysteriously as it appears.

In response to your question about a specific test to determine this condition, the answer is that a tissue biopsy is necessary to prove the diagnosis and to exclude a variety of other conditions whose symptoms mimic endometriosis. Without a biopsy, all diagnoses of this condition are guesses, though they may be educated guesses.

You certainly are correct in your concern about the birth-control pill being prescribed for your daughter, not only because of her symptoms since she started taking this drug, but also because studies in Great Britain's London School of Hygiene and Tropical Medicine have shown that women taking the Pill had death rates far higher from heart and circulatory disease than comparable women who did not take the Pill. The professors from both the London School and Oxford University, who directed the research, declared in 1978 that all dangers and risks in taking the Pill had been previously underestimated.

Dr. Herbert Ratner, editor of "Child and Family Quarterly" and one of the first public health officers to point out the Pill's dangers, states: "The [British] studies indicate that death from the Pill just from circulatory diseases is of epidemic proportions."

These scientific studies, as well as those which link the Pill to liver cancer, breast tumors, etc., should be sufficient to make your physician just as frightened of using the Pill as you already are. This intelligent fear should provide the necessary motivation for your own doctor, as well as others you might consult, to carefully review the correctness of the diagnosis as well as the large variety of management options.

Q I recently have been diagnosed as having endometriosis, a condition which I've apparently had for some time and am just finding out about. My symptoms include extreme pain and loss of blood during menstruation, and on occasion I also notice a low back pain as well as discomfort during urination and bowel movements.

My doctor prescribed Danocrine--four per day for two months. Although the doctor didn't actually say so, my pharmacist says this drug usually is prescribed in hope of preventing surgery, and I can expect some side effects.

Can you provide me with more information on Danocrine? Is it a hormone derivative? What kind of side effects can there be? Is it less risky than surgery, and is it effective in treating endometriosis?--B.R.

A I hope your doctor did not prescribe Winthrop's Danocrine as your first treatment, since the product information clearly states that Danocrine is indicated for the treatment of endometriosis ONLY for those patients who cannot tolerate other medications or who fail to respond to other effective drug therapy. The reason for this is because the lowest effective dose of this powerful drug is yet to be determined. Danocrine acts on the pituitary gland, the master endocrine gland of the entire body, by inhibiting the output of certain hormones so that ovarian function is suppressed. This, of course, results in cessation of menses and of ovulation which usually returns within 60 to 90 days after this therapy is discontinued.

*Danocrine
as
endometriosis
treatment*

Since you ask about this drug as an alternative to surgery, let me respond by quoting directly from the prescribing information: "Danocrine is not indicated in those patients where surgery alone is considered the treatment of choice."

The adverse reactions of this androgenic (masculinizing) hormone include acne, water retention (edema), abnormal hair growth (hirsutism), decrease in breast size, deepening of the voice, oiliness of the skin or hair, weight gain, and, rarely, hypertrophy of the clitoris. Other manifestations include blushing; sweating; vaginitis including itching, dryness, burning, and vaginal bleeding; nervousness and emotional instability; hair loss; change in sex drive; elevated blood pressure and, rarely, pelvic pain.

There are plenty of other reactions on the central nervous system, gastrointestinal tract, musculoskeletal system, and urinary tract. You should read this section of the prescribing information carefully, as well as the paragraphs which warn patients to discontinue the drug if they should become pregnant because of its masculinizing effect on the fetus.

If you develop some of these male features, don't count on their disappearing, since the prescribing information states gloomily, "Some androgenic effects may not be reversible even when drug administration is stopped."

I hope this brief answer of mine gives you the kind of information which your doctor and pharmacist should have provided in the first place.

Q

I am 30 years old and recently had surgery because of a pelvic mass. My condition was diagnosed as endometriosis, and one ovary and tube were removed. My doctor has prescribed Danocrine (danazol) treatment for six to eight months. I was shocked at the cost of this drug, and I am very apprehensive about taking a drug that suppresses the natural function of my pituitary gland. Just what are the real dangers of this treatment? My doctor says only that I may experience some hair growth and oily skin.

Please reply as soon as possible. You are the only person I can depend on for the facts.--S.P.

A

Winthrop's Danocrine has the following information listed under indications: Until additional studies have been completed which define the lowest clinically effective dose, Danocrine is indicated for the treatment of endometriosis amenable to hormonal management and only for those patients 1) who cannot tolerate other drug therapy, 2) in whom other effective drugs are contraindicated, or 3) who fail to respond to other effective drug therapy when given in adequate doses.

Under "Warnings," this statement appears: Further studies are ongoing to define the lowest clinically effective dose of Danocrine, brand of danazol. Consequently, at the present time, Danocrine should be limited in its use to the select group of patients mentioned in the "Indications" section.

While I am glad your doctor told you about the possibility of hair growth and oily skin, I regret he did not also mention the adverse effects I discussed in my previous answer to B.R.

I'm not surprised that you, or anyone else who remembers from high school biology that the pituitary is the master endocrine gland of the entire body, would be apprehensive about taking a drug that suppresses the natural function of this gland. I hope your doctor has powerful reasons for prescribing this powerful medicine.

*Mendelsohn's
endometriosis
treatments*

The following are my recommendations for treatment of endometriosis:

1. Avoid surgery at all costs.
2. Avoid hormones at all costs.
3. Pay close attention to your nutrition and get proper exercise.
4. Use whatever analgesics and sedatives are necessary to relieve your pain. Herbal teas, codeine, or even liquor, as far as I'm concerned, are safer than Danocrine.
5. Refrain from sexual activity during the menstrual period and for a week afterwards.
6. If your menstrual periods and/or ovulation are irregular, use the Billings Method to help determine the time of ovulation. (Information is contained in "The Billings Method," by Dr. Evelyn Billings, published by Random House, \$12.95.)
7. Stay away from all methods of birth control (the Pill, IUD, tubal ligation, induced abortion, a diaphragm, condoms, etc.).
8. If you agree with me that today's epidemic of endometriosis in large part results from physicians' promiscuous prescribing of female sex hormones, try to figure out who is to blame for your condition. Was your mother among the six million women who between 1940 and 1980 were treated with DES? Did your doctor give you the Pill (for contraception? for acne? for irregular periods?), all the while telling you it was perfectly safe?

Q

Both for contraceptive purposes and because my periods had become irregular and I was spotting heavily, I decided to go on the Pill when I was 19 years old. At that time my doctor could find nothing wrong with me, and he agreed to put me on the Pill. About a year ago, I decided to stop the Pill because I had heard that being on it for five years was enough. I did not have another menstrual period for five months. Last May, I went to another doctor who prescribed Provera, which I took for five days. I did menstruate, but I haven't done so since, only some light spotting for about five days.

Doctor, am I likely to be sterile? What can I do to find out? My husband and I want to have a baby, and the doctor says that if I don't conceive shortly, he may have to put me on fertility pills.--Worried

A

*Regaining
fertility
after taking
the Pill*

In her landmark book, "The Doctors' Case Against the Pill" (Doubleday Dolphin, \$6.50), Barbara Seaman devotes an entire chapter to sterility and the Pill. She asks, "Do young women know the Pill may make them sterile? Does the typical pill-prescribing gynecologist warn them about the danger of sterility? In far too many cases, the answer to these questions is 'No.'" Seaman also cites the American Journal of Obstetrics about the possibility of "...subsequent infertility before oral contraceptives are prescribed."

Doctors attribute sterility caused by the Pill to such local injuries as damage to the lining of the uterus or to the ovaries. These injuries may be related to nutritional deficiencies caused by the Pill. Thus, abnormal Pap smears in Pill users sometimes can be returned to normal by extremely large doses of folic acid, a deficiency of which may occur in women who take birth control pills. Therapeutic doses of certain vitamins, including folic acid, vitamin E, and vitamin B-6 may help a woman whose periods have stopped to achieve normal fertility.

As many as five percent of all women who use birth control pills experience temporary infertility, and their doctors may treat this condition with powerful drugs such as Clomid or, in your case, with a progestational agent such as Provera. I hope you have carefully read the three columns of contraindications, warnings, precautions, and adverse reactions (including such risks to the fetus as congenital heart defects and limb reduction) which accompany the prescribing information for Provera.

Ovulation occurs in about 70 percent of the women who take Clomid, and pregnancy results for about 40 percent. The incidence of multiple pregnancies is eight percent, a figure which is six times the normal.

If hormonal treatments don't seem to be the answer for you, you might want to read Ms. Seaman's other bestseller, "Women and the Crisis in Sex Hormones" (Bantam, \$3.50). Although nobody has conducted studies on nutritional supplements that may help a woman become fertile again, Ms. Seaman relates the history of a patient who had no menstrual periods for 18 months after she gave up the Pill. Her periods returned after she followed a nutritionist's advice and took vitamin E, wheat germ oil, B-complex, vitamin C, zinc, and selenium.

I certainly do not want to downgrade the seriousness of your situation. (Did your doctor inform you about possible consequences when you started taking the Pill?) I hope this information will enable you to reach further decisions reasonably.

Q

Can you give me any information on Clomid or where I can go to read up on it? Are there any known dangers to the infant or the mother?--Mrs. E.J.

A *Risks of Clomid*

Don't bother looking up Clomid in the Physicians' Desk Reference because you will find only the instruction to write to the manufacturer of this fertility drug, Merrell-National. But if you go to your public library and look at the Fourth Edition of "AMA Drug Evaluations" or "The Physician's Drug Manual" (Doubleday), you will find that 10 percent of women given Clomid develop flushes and 14 percent develop ovarian enlargement. Less commonly, massive abnormal cystic enlargement of the ovaries may occur, accompanied by pain. The maximal enlargement of the ovary does not occur until seven days after therapy is discontinued. The manufacturer recommends conservative treatment for this cystic enlargement, "unless surgical indication for laparotomy [operation through the abdomen] exists."

Not only can Clomid affect the ovaries, but its influence on the eyes include blurred vision, double vision, spots before the eyes, after-images, sensitivity to light, floaters, waves, cataracts, detachment of the posterior vitreous, spasm of the blood vessels, and thrombosis of the retinal arteries. Other side effects include abdominal distention, bloating, abdominal or pelvic pain and soreness, nausea and vomiting, increased appetite, acute abdomen, constipation, diarrhea, breast discomfort, abnormal menstrual bleeding, dryness of the vagina, headache, dizziness, lightheadedness, vertigo, nervous tension, insomnia, fatigue, depression, increased urinary frequency and/or volume, skin rashes, hair loss, dryness of the hair, weight gain or loss, jaundice, and fluid in the abdomen.

Make sure that you are not already pregnant when the doctor prescribes Clomid. "The Physician's Drug Manual" lists the birth defects which have been linked to this drug, among them congenital heart disease, Down's syndrome, clubfoot, congenital intestinal conditions, hypospadias (abnormal position of the urethral opening), small head, harelip, cleft palate, congenital hip displacement, birthmarks, undescended testes, extra fingers, conjoined twins, inguinal hernia, umbilical hernia, fused fingers, funnel chest, muscle disorders, dermoid cysts, spina bifida, and other defects.

You also should know that a variety of laboratory values, including some liver function tests and thyroid hormone tests, may be elevated when you take Clomid. And Clomid is contraindicated in anyone with a history of liver disease, thyroid or adrenal malfunction, or ovarian cysts. And, as stated in my previous answer, about eight percent of women who become pregnant on Clomid will have multiple births, usually, but not necessarily, twins.

Why take Tylenol at all?

As I write this, seven people in the Chicago area are known to have died from cyanide which was found in Extra-Strength Tylenol (acetaminophen). Officials at all governmental levels are trying to find ways to prevent this kind of tragedy from ever happening again, the current favorite solution being mandatory seals on all over-the-counter drugs. Thousands of investigators are working around the clock to discover how the cyanide got into the capsules. Perhaps "the kook" theory will turn out to be correct, or perhaps industrial contamination will be uncovered. But even if all those mysteries are never solved, there are some definite lessons in this for you and for me.

There is an obvious point in the distribution of Tylenol where the deadly link can be broken. People simply can elect not to take it. But why would anyone reject this wonder drug which guarantees relief of minor aches, pains, headaches, and fever and which contains no aspirin (especially when, as in my case, free samples are sent to the home)? After all, now that people have been finding out the dangers of gastrointestinal

hemorrhage, ringing in the ears, etc. from aspirin, haven't they heard their doctors advise them to take Tylenol instead?

In 1979, the University of Colorado School of Medicine had recorded more than 2,500 overdoses from acetaminophen during the three preceding years. Fourteen percent of these patients had developed blood levels of the drug which were high enough to cause liver damage, and three of these patients had died. Acetaminophen overdose can cause jaundice, bleeding, and fatal liver failure. Obviously, a dose which can be normal for the majority of users may constitute an overdose in a minority of users. Furthermore, in case of overdose, acetaminophen (Tylenol included) may be more lethal than aspirin and considerably more difficult to treat. The American Academy of Pediatricians has recommended that "Parents should be educated to respect this drug as a potential poison, just as they do aspirin." If you are convinced that Tylenol is safer than aspirin, Harvard Medical School's Dr. Frederick H. Lovejoy, Jr., points out that that safety may be an illusion: "Because of the relatively short duration of clinical experience with acetaminophen, the number of documented adverse effects associated with its use is less [than aspirin]," says Dr. Lovejoy. In addition, Tylenol, like many other drugs, can interact adversely with other medications. For example, acetaminophen strengthens the action of some anti-hypertensive drugs. Therefore, whether poisoned with cyanide or not, Tylenol is a drug to be wary of.

The Tylenol tragedy seems to have been limited to seven victims because of some lucky coincidences and some highly astute observations by some policeman and firemen. But how many similar cases throughout the country have gone totally undetected? Since no-one knows the extent to which Tylenol or other over-the-counter drugs might be laced with cyanide, I recommend that a national registry be set up to collect reports of every death in this country that has not been satisfactorily explained and to investigate the possibility of medication poisoning.

What will doctors, now bereft of both aspirin and Tylenol, turn to? Is it possible that they may give up their belief in "better living through chemistry" and recommend that people with headaches try cold compresses, rest, and maybe a cup of tea? I sincerely hope so, especially when doctors counsel women. In keeping with my belief that women are the chief victims of modern medicine, did you notice that five out of the seven Tylenol fatalities were women? But perhaps the people themselves have already given up their belief in magic capsules. The last I heard, sales of over-the-counter drugs in the Chicago area had dropped by 40 percent.

(From Newsweek, October 11, 1982)

Officials at McNeil Consumer Products Co. conceded that they routinely use cyanide at Tylenol manufacturing plants... It is used in chemical tests that ensure the absence of lead in the ingredient povidone, a common pharmaceutical binding agent. McNeil says it keeps the cyanide in small amounts in a laboratory separated from the manufacturing process. Access, the company says, is strictly limited to employees.

From the time we began publication seven years ago, the annual subscription price of The People's Doctor Newsletter has remained at \$18.00. Since rising costs make it impossible for us to continue publishing at that price, the new annual subscription rate will be \$24.00. Individual back issues will now be priced at \$2.50.

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Another View

by Marian Tompson
Executive Director,
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It was only a few months ago that Parlodel, a milk suppressant given to women who do not breastfeed after childbirth, was discussed in The People's Doctor Newsletter (Vol. 6, No. 9). Concern was expressed, not only about the safety of this relatively new therapy, but also about the negative effect it might have on a woman's mothering. These concerns evidently are shared by others; we have since learned of a hospital in Detroit where Parlodel was discontinued after the staff was given the information contained in that Newsletter.

Therefore, it came as quite a surprise to see an exhibit at a recent meeting of the American College of Obstetrics and Gynecology in Chicago which heralded Parlodel as "a significant advance in the treatment of female infertility." "Is this safe?" I asked the Sandoz representative at the booth. "Oh, it's perfectly safe," she replied, handing me a large colorful booklet. "You can read all about it in here."

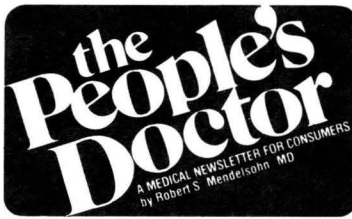
Well, I read it all, and I was left confused and uneasy. For one thing, the numbers they used never seemed to add up. I learned that when using Parlodel (which lowers prolactin levels), 80 percent of 187 patients began menstruating in an average of 5.7 weeks; 88 percent of 479 women ovulated; 66 percent of 492 conceived, and 1,276 women got pregnant. These pregnancies yielded 1,109 live births and four still-born infants, among whom there were 37 cases of congenital anomalies. Sixty-eight percent of the women had adverse reactions, a number which Parlodel's manufacturer admits is high. But we are reassured that the nausea, headaches, dizziness, fatigue, abdominal cramps, vomiting, etc. were generally mild to moderate in degree.

But, bearing in mind that Parlodel is being given to assist a woman in getting pregnant, read just one of the warnings in the prescribing information: "If pregnancy occurs during Parlodel (bromocriptine mesylate) administration, treatment should be discontinued immediately. Careful observation of these patients throughout pregnancy is mandatory. Small prolactin-secreting adenomas not detected previously may rapidly increase in size during pregnancy. Optic nerve compression may occur, and emergency pituitary surgery or other appropriate measures may be necessary."

It's true that since I am not a doctor, I am unfamiliar with a lot of medical terminology, but the meanings of "mandatory," "optic nerve compression," and "emergency pituitary surgery" are pretty clear. It's hard for me to see how a woman could enjoy a pregnancy if she were haunted by those possibilities.

I also was curious as to whether use of Parlodel might repress the breastfeeding of a child who was conceived with the help of this drug. Although Sandoz' representative assured me it was no problem, I wrote to the company, receiving a prompt reply to my "interesting question." It seems that information has been collected on 1,410 pregnancies resulting in 1,213 births of 1,241 babies whose mothers took Parlodel to assist in conception, but "it is unfortunate that no records were obtained concerning whether these women were able to breastfeed or chose to breastfeed."

If infertility is a problem, your first step might be to get together with other couples seeking information and solutions. RESOLVE, a nationwide, non-profit organization grew out of just such a meeting held nine years ago in Boston. With chapters now in most major cities, this group offers telephone counseling, referral, support groups, literature, and a newsletter. For information, write RESOLVE, P.O. Box 474, Belmont, Mass. 02178 or telephone (617) 484-2424.



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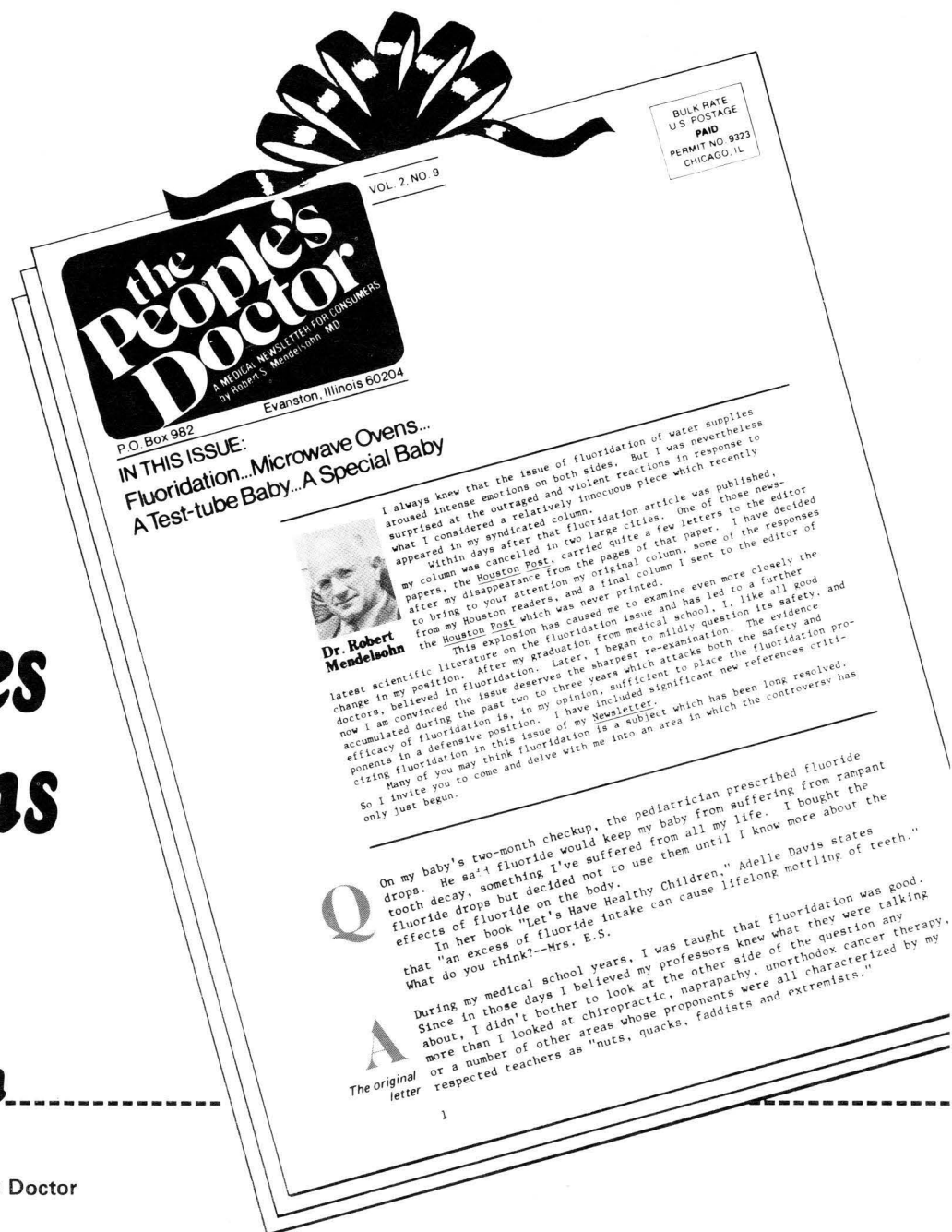
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