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A MEDICAL NEWSLETTER FOR CONSUMERS
by Robert S. Mendelsohn, MD

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IN THIS ISSUE:

Bendectin removed from the market

Dr. Robert Mendelsohn

Ever since I began writing my syndicated newspaper column and this Newsletter, I have been answering questions about the anti-nausea drug, Bendectin. Three years ago, I used my column as a forum, inviting readers to share their remedies for morning sickness with one another. I warned that Bendectin was a dangerous drug, named by Madison Avenue techniques to sound like a benediction--when it was really a curse.

Today, I would like to be able to assure you that Bendectin need no longer even be considered. It finally has been taken off the market by its manufacturer. But, unfortunately, its scandalous backwash continues to threaten many American mothers. In the pages of this Newsletter, I had predicted that obstetricians, infuriated by the loss of their favorite but unproven drug, would extract revenge from women with morning sickness. I learned, just before sitting down to write this introduction, that my somber prediction has become a reality.

Warren H. Pearse, M.D., executive director of the American College of Obstetricians and Gynecologists, told Medical World News that the loss of Bendectin left a "significant therapeutic gap"--exactly the same words used by Merrell-Dow in their "Dear Doctor" letter. And Henry Foster, M.D., OB/GYN chairman at Meharry Medical College told Medical World News, "We'll probably see a greater number of women hospitalized for this condition so they can receive intravenous fluid therapy...."

The terrifying thought is that obstetricians have the capability to make their threats come true! The sinister power of doctors to achieve this self-fulfilling prophecy makes "the obstetricians' revenge" a direct descendent of the voodoo curses of the primitive witch doctor.

The secondary lesson of the Bendectin disaster is to be suspicious of drugs. The primary lesson is to become aware that, all too often, the modern doctor is barely a step away from the witch doctor of old.

Many of you are aware that Merrell-Dow Pharmaceuticals has removed its morning sickness anti-nausea drug, Bendectin, from the market. Within the past year, three major medications have been pulled off drugstore shelves. Because of reports of death associated with the drugs, Johnson & Johnson had to withdraw its analgesic, Zomax, and Eli Lilly stopped the sale of its anti-arthritic, Oraflex. In the case of Oraflex, the Justice Department is considering taking criminal action against Eli Lilly for allegedly failing to report those deaths. While both Zomax and Oraflex are new, Bendectin has been around for more than a quarter of a century and has been prescribed for tens of millions of women.

Objects of lawsuits

Linked to cases of limb reduction, Bendectin is the object of hundreds of lawsuits on behalf of damaged children. (Limb reduction, as many older readers will recall, was the major adverse reaction to Thalidomide, Bendectin's predecessor for morning sickness in pregnant women. Merrell was involved in the manufacture of Thalidomide as well as the manufacture and sale of Bendectin.)

According to the Wall Street Journal (June 10, 1983), Merrell-Dow claims the drug is safe but that its production was discontinued because the company did not want to keep up payments for liability insurance ($1 million monthly) to defend itself against lawsuits. I quote from the Wall Street Journal because its authoritative information on medicine certainly rivals--and often precedes--that available to physicians in their medical journals. Indeed, the "Dear Doctor" Mailgram sent to physicians by Merrell-Dow to explain Bendectin's withdrawal is dated June 9 and did not reach most of us until after the Journal article had appeared, even though Merrell-Dow's first sentence in that "Dear Doctor" letter states that they "have taken all possible steps to ensure that you are the first to know."

In that "Dear Doctor" Mailgram, Merrell-Dow complains, "Bendectin is a victim of these litigious times, and the results of litigation may not always be consistent with scientific facts." This charge, which does not appear in the Wall Street Journal article, is designed to strike a responsive chord in the heart of every physician who is frustrated at his rising malpractice insurance rates. On the other hand, the "Dear Doctor" letter fails to carry the Journal's information that, financially speaking, Merrell-Dow is taking a bath on Bendectin. The drug's annual U.S. sales peaked at about $15 million a few years ago, but the publicity about its possible damaging effects on the unborn fetus have significantly reduced the number of Bendectin pills sold. To compensate, in the past two years the company twice substantially raised its price so that, before its withdrawal from the market, Bendectin retailed for about $1.00 per tablet. The company spokesman admitted, "But we figured we can't raise the price of it any more...and we don't want to raise prices of our other drugs" to compensate for Bendectin's declining sales performance.

Congenital defects

However, neither the Wall Street Journal article nor the "Dear Doctor" letter mentioned what may be the more basic reason for Merrell-Dow's decision, i.e., the linking of Bendectin to congenital defects other than the foreshortening of the extremities and absence of fingers and toes. According to studies from the Departments of Epidemiology and Public Health and Obstetrics and Gynecology, Yale University School of Medicine (American Journal Obstetrics and Gynecology, December 18, 1982), mothers of infants with congenital malformations in general showed an increased likelihood of having used Bendectin. A statistically significant association was observed between the occurrence of pyloric stenosis (a closing off of the outlet of the stomach which may necessitate surgery in the early newborn period) and exposure to Bendectin. Indeed, infants with pyloric stenosis were more than four times as likely to have mothers who used Bendectin. But damage to the skeletal system and gastrointestinal tract is only part of the story.

The study reported in the above journal also linked the use of Bendectin with a threefold increase of risk of defective heart valves in the offspring. This study at the Yale University School of Medicine is not alone in linking congenital malformations to Bendectin. Three other investigations, reported in The Journal of the American Medical Association (1981) and American Journal of Obstetrics and Gynecology (1977), had previously shown an elevated risk of gastrointestinal malformations, par-

ticularly esophageal atresia (failure of the esophagus to develop) and gastrointestinal atresia (failure of other parts of the intestinal tract to develop) in infants of mothers who were prescribed Bendectin. Pyloric stenosis, like other gastrointestinal atresias, is a constriction of the digestive tract, and the Yale study concludes: "More than one in 10 cases of pyloric stenosis may be due to maternal use of Bendectin." (How I wish that in my earlier years of pediatric training and practice, I had been taught to ask the parents of children with the many cases of pyloric stenosis that I treated what drugs their doctors had prescribed during their pregnancies. Instead, I was taught to say, when faced with parents of a malformed child, "Don't look behind; just look ahead." This massive cover-up of the sins of obstetricians by pediatricians over the last 40 years is one of the still-to-be revealed scandals of modern medicine.)

Just because Bendectin production has been discontinued does not mean that you can relax. Merrell-Dow's "Dear Doctor" letter assured doctors that the company is trying to maintain current supplies of Bendectin in the marketplace sufficient to fill the needs of current patients. Merrell-Dow states, "There is no reason for these patients to stop medication."

Therefore, we can expect that at least some doctors may fail to tell women who are currently on Bendectin the scientific evidence that has been reported in this Newsletter. If you or any members of your family or your friends are still taking Bendectin, the patients should be informed of the evidence linking Bendectin to skeletal, gastrointestinal, and cardiac malformations. Ask the treating physicians if they agree with Merrell-Dow's claim that "There is no reason for these patients to stop medication."

Even though it took all these years before action was taken to remove Bendectin from the marketplace, the important lesson to be learned is that any drug prescribed by a doctor for a pregnant woman is potentially dangerous to her offspring.

What are doctors going to do in the future when this drug, the only one indicated for relieving morning sickness, is no longer available?

Alternatives to Bendectin

In their "Dear Doctor" letter, Merrell-Dow claims that the loss of Bendectin "will create a significant therapeutic gap" because Bendectin "has been long-valued by physicians in the treatment of nausea and vomiting of pregnancy." The implications of this not-so-subtle threat were brought home to me last weekend when some medical students and house officers reported they had overheard doctors planning what I term "the obstetricians' revenge." Faced with mothers with morning sickness, some obstetricians are planning to tell them morning sickness can lead to death (because, in rare cases, the vomiting can be severe enough to cause dehydration).

Based on this threat, they will hospitalize women with mild-to-moderate cases of morning sickness for intravenous fluid therapy, and then will report that if Bendectin had been available, such hospitalizations would not have been necessary. Intravenous fluids certainly are an appropriate method of treatment for the rare, truly severe case of dehydration from massive vomiting, without danger of deforming the fetus. But, in the mild-to-moderate cases, the risk of intravenous fluid and all the attendant risks of hospitalization make this brand of "preventive medicine" so bizarre that I remind you of the maxim, "If this is preventive medicine, I'll take my chances on disease."

This "obstetricians' revenge" parallels the "pediatricians' revenge" I have written about in earlier Newsletters. Over the last several years, parents in one country after another (first Great Britain, then Japan, and more recently the United States) have rejected the whooping cough vaccine. Angered by the refusal of the laity to accept

the "holy water" of the medical priesthood, pediatricians have created "epidemics" of whooping cough by diagnosing that disease whenever a patient clears his throat.

The "pediatricians' revenge" and the "obstetricians' revenge" are two examples of the dangerous retaliatory measures doctors can take which all patients must guard against. Therefore, every pregnant woman with morning sickness must be careful of radical advice that may be given by the doctor. If the doctor wants to prescribe anti-nauseant drugs other than Bendectin, if he wants to hospitalize her, she ought to get a second opinion from another doctor, from a midwife, from a nutritionist, or from an older woman who lived in the era when morning sickness was considered a normal part of pregnancy, something that wasn't even discussed with a doctor.

Furthermore, even though statutes of limitation may prevent legal action in some cases, parents of every child born during the past quarter century with a congenital malformation (heart, bones, intestinal tract) must immediately call for the hospital records and the doctors' office records to see whether Bendectin had been prescribed.

For those of you who are interested in broader societal issues, Merrell-Dow's "Dear Doctor" letter says: "It may be that our action will highlight once again the need for our society to reflect upon the effect our nation's current attitude toward litigation is having upon the health care community." Of course, this comes as music to the ears of doctors, plagued as they are by the ever-rising costs of malpractice insurance. Yet (with all their defects), litigation and the court system presently offer the only mechanism for obtaining the large amounts of money necessary to care for the rest of their lives for infants and children who have been damaged by medical technology (whether Bendectin, in the case of obstetricians, or pertussis vaccine, in the case of pediatricians).

Therefore, in the backwash of Merrell-Dow's "Dear Doctor" letter, we can expect to see new attacks on state legislatures by doctors seeking further limits on medical malpractice actions (shorter statutes of limitations, M.D. arbitration panels, ceilings on financial compensation, etc.).

Throughout its 27-year history, Bendectin never has been proven safe and effective in the treatment of morning sickness. After all the legal, societal and scientific arguments, the bottom line for every pregnant woman remains: "Don't let your doctor prescribe any medication during your pregnancy unless he can prove to your satisfaction that he is treating a life-threatening condition."

Potpourri

Q

Recently, you advised a woman whose twins had repeatedly been exposed to ultrasound in the womb that she should keep the hospital and doctors' records in a safe place for 20 years or more.

Does this advice apply to personal health records, such as those of my father and myself? Does this apply to lab results only, or does it include the doctor's notes and comments?

I ask these questions because we have tried to get our own records. In one case, we were advised that they "could not send the file or the copy of the file" to us. In another case, we were ignored, and in a third incident, we were sent some paltry copies of some lab results.

Does the Public Disclosure law apply in these instances? How does one get a copy of his records, and how much of his record is the patient entitled to have?--H.J.

Obtaining medical records

Even though courts have upheld the right of patients to their own medical records, some doctors and hospitals have been dragging their feet on this issue. So instead of expecting a prompt, courteous response from doctors and hospitals, a patient should carefully plan strategy for obtaining his records. If you are given only the lab results, write again and say you want all your records, including the physician's order sheets, the nurses' notes, the doctor's progress notes, the x-ray reports, the operating room records, the anesthesiology record, and anything else that has been written down.

If you receive no response to your letter, pay a personal visit to the hospital administrator. If one visit doesn't do it, consider making a return visit with a bunch of tough-looking relatives and friends. If your brother-in-law is a lawyer, ask him to send a letter on his office stationery to the hospital and to the doctors, but remember that even lawyers sometimes have trouble getting hold of unaltered (or perhaps "undoctored") medical records.

Above all, don't give up hope. Now that insurance companies, employment agencies, personnel departments, and practically everyone else seems to have access to your "confidential" medical record, doctors and hospitals are finding it increasingly difficult to justify keeping the records secret from the patient himself.

Q

After reading your recent Newsletter on bedwetting (Vol. 7, No. 6), I just wanted to share some information with you. All your comments on enuresis were good and valid, but one additional piece of information should be added. In chiropractic, we have used the adjustment of the second sacral segment for enuresis. It is interesting to note that this is also an acupuncture point for the bladder.--Dr. Jason P. Schwartz, Stuart, Florida

Q

On the subject of bedwetting, the chiropractic profession has had considerable positive results with this problem. Neuroforaminal encroachment in the cervical spine can interfere with the phrenic reflex and thus produce the problem.--Dr. F. H. Barge, La Crosse, Wisconsin

A

Chiropractors on bedwetting

Your letters serve to remind me, as well as my readers, that M.D.-physicians have no monopoly on the art of healing.

Q

For the past 12 years, my husband has been taking various drugs for his high blood pressure. We have experimented with dosage, hoping he could cut down, but even though he has lost 20 pounds, his pressure quickly rises to 180/120 if he stays off the medication. We have a self-operating mercury type kit, and we take his pressure twice daily.

When I take my husband's blood pressure while he is sitting up, it reads 150/100. He then lies down, and it reads 120/80. If he sits back up, the pressure jumps higher again. All this happens within a matter of minutes. We have asked the doctor for an explanation, but he says he doesn't know. Do you know?--S.S.

Why blood pressure readings fluctuate

Your letter demonstrates the inadequacy of most blood pressure measurement. The doctor takes the patient's blood pressure, both he and the patient assuming that the instument which is used to measure that blood pressure is highly accurate and can give reliable readings that can be compared with each other. Yet, you have learned for yourself some of the vagaries of blood pressure readings which every doctor has been taught.

You now know that the blood pressure differs depending on the position and posture of the patient. You have learned that changing from a prone position to a seated one influences the reading. Other factors which influence blood pressure readings include the time of day, before or after mealtime, exercise, and the size of the blood pressure cuff (particularly in obese adults and little children).

For a variety of reasons, blood pressure may be different in one arm than in the other. It may be influenced by who takes the measurement--the doctor, his nurse, a relative of the patient. It may be influenced by where it is taken--the doctor's office, the drug store, the automatic blood pressure machine in an airport, your own sofa. In addition, blood pressure is affected by a variety of drugs other than antihypertensives. You always should be concerned (as should every doctor) about the frequency with which the instrument of measurement is calibrated. And how about your husband's state of mind at the different times you are taking his blood pressure?

All doctors should know the marked variations in blood pressure readings so that they will not unnecessarily prescribe dangerous medications for their patients. Find a doctor who knows the answers to your questions and who will explain them to you.

New ulcer drug—Zantac—hits the market

Tagamet, the all-time best-selling ulcer medication, is about to lose its monopoly position. In July, two pharmaceutical companies, Glaxo and Hoffman-La Roche will begin selling and marketing Zantac, Glaxo's new anti-ulcer drug. (The generic name for Tagamet is cimetidine, while the generic name for Zantac is ranitidine.)

A veritable army of salesmen stands poised to descend on your doctor --the two companies responsible for Zantac have a combined sales force of 1,100. Not to be outdone, SmithKline, manufacturer of Tagamet, has bolstered its sales force to 825 (The Wall Street Journal, June 13, 1983). The Zantac legions will be telling your doctor that Zantac, with its twice-a-day dosage, is more convenient than Tagamet, which usually is given four times a day. On the other hand, the Tagamet detail men will emphasize Tagamet's price advantage ($1.00 per day) versus the predicted $1.25 per day for Zantac. They also will emphasize the availability of injectable Tagamet as well as the FDA's approval of Tagamet for long-term therapy in the prevention of recurring duodenal ulcers. Therefore, you can expect your doctor to be under great pressure to prescribe more Tagamet as well as the newly-introduced Zantac.

For several reasons, you also can expect your doctor to be quite vulnerable to massive onslaught of this sales army, first because scientific considerations are of secondary importance. Professor James W. Preston, M.D., University of Connecticut School of Medicine, last year told financial analysts that the competition between Tagamet and Zantac "will be determined more by marketing forces than by scientific merit." Second, the brainwashing of doctors by SmithKline over the last several years has

included large numbers of full-page, four-color ads for Tagamet showing the drug name and the pills, with nary a word about the indications, warnings, precautions and adverse reactions. The euphemism for this FDA-approved selling technique is "reminder ads." Will similar ads be directed at doctors by Zantac's manufacturers?

Third, the full range of Zantac's side effects will not be known until it becomes widely used. After all, in 1978, the prescribing information for Tagamet was only four columns long, and the adverse reactions amounted to about two inches of type. By 1981, the prescribing information for Tagamet covered six full columns of the Physicians' Desk Reference, and the space devoted to adverse reactions increased another inch. Now, in 1983, the prescribing information is almost seven columns long, while the adverse reactions measure almost half a foot!

Between 1981 and 1983, an entirely new section on impotence appeared, in addition to a re-listing of some of the other side effects which include bone marrow destruction, hepatitis, pancreatitis, and enlargement of the male breast. However, even if a doctor has carefully read the new prescribing information every year, unless he is an afficionado of The Wall Street Journal, he is unlikely to know that Tagamet carries "such occasional side effects as brief spells of confusion in the elderly." (Might this Tagamet-induced confusion be confused with the burgeoning number of patients being diagnosed as having Alzheimer's disease?)

The detail men for Zantac will provide the doctor with information about precautions and side effects that he should consider when prescribing the drug. However (just as with other drugs), the drug company will not provide that information directly to you, the patient, because the doctor is regarded as a "learned intermediary" between the drug company and the patient.

But you and I and the drug companies know that the "learned intermediary" is more a theoretical concept than a practical reality. The person who is prescribed this new drug must set up his own defenses against the predictable barrage of Zantac prescribing. So if your doctor tells you about that wonderful new drug, Zantac, ask him what he knows about its side effects. Ask him what anyone knows about its side effects. Ask him if there is a special reason why you should serve as the experimental subject for his newly-introduced drug. Ask him, just as you should ask any doctor who tries to prescribe Tagamet for you, if he knows how to get rid of your peptic ulcer without drugs. Take a neutral position in the Tagamet/Zantac war: If your doctor can't help you without turning to his prescription pad, find yourself a doctor who can.

"MalePractice: How Doctors Manipulate Women," Dr. Mendelsohn's latest book, is now available in paperback from Contemporary Books ($6.95).

"Confessions of a Medical Heretic" is available from WarnerBooks ($3.25).

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Another View

by Marian Tompson
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Richard was trying to be helpful--he hadn't meant to cause any trouble. But after learning that his friend's wife, Shirley, was taking Bendectin, Richard dug up several pertinent issues of the People's Doctor Newsletter and gave them to his friends to read. Little did he dream that, as a result, Shirley would be forced to find a new obstetrician before the month was out.

After she had read the Newsletters, Shirley had decided to show them to her obstetrician. "I was now a little nervous about continuing to take the Bendectin he had prescribed," she recalls, "and I asked whether there was anything else I could do to help relieve my morning sickness. His reaction astounded me. In fact, he got so angry I was afraid that he might physically hurt me. He spent much more time yelling at me than he had ever spent talking to me on previous visits. As he stomped out of the room, his parting words were, 'Why don't you let those people treat you!'"

So Shirley ended up with Dr. B. who took a more conservative approach to morning sickness. "First we take a look at what you are eating," he explained to Shirley. "We recommend small frequent meals, eating good food and staying away from greasy and spicy foods and empty calories. If your nausea persists, we'll try B6 supplements. If the supplements don't work, we then let you read the package insert for Bendectin. If you still want to take Bendectin after reading the insert, we'll have you sign the insert which is then kept as part of your file."

Clearly Dr. B's approach was an improvement, but there are a lot of other suggestions he could have offered before offering Bendectin. For example, my daughter, Melanie, found that what she ate made a difference, and how she moved also had an effect. During her first pregnancy, she always gave herself an extra hour in the morning to get ready to go to work. By moving slowly while she dressed and made breakfast, she found she could keep that queasy feeling away. Jumping up out of bed and rushing around was certain to result in nausea. High protein snacks taken frequently, even while waking during the night, also helped.

In "The Pregnant Woman's Comfort Guide" (Prentice-Hall, Inc., 1983, $14.95), author Sherry Lynn Mims Jiminez suggests a variety of non-medical ways to deal with the discomforts of pregnancy. She states that new research has shown that for many women morning sickness may be due to low blood sugar: "This temporary condition can occur in pregnancy due to the excessive protein requirements of the developing fetus." The problem is more pronounced in the morning because the woman hasn't eaten all night. Yet at the same time, her stomach has been secreting acids which cause further nausea. Therefore, Ms. Jiminez advises neutralizing the acid by drinking milk or eating an apple or potato without the peel. Soda crackers also can help. But if you can't face food, Ms. Jiminez recommends taking two calcium tablets which should settle your stomach enough so that you can eat in about half an hour. Frequent snacks of protein-rich food keep blood sugars at a good level. Among the author's many recommendations for relief are: sucking or chewing on ice chips, applying a cold cloth or ice pack to the throat, slow mouth breathing, and putting pressure on several acupressure points in the ear.

In retrospect, Shirley and her husband were grateful for their Bendectin "encounter." They learned how to deal safely with a troublesome complaint, and they found a doctor who was not threatened by their questions and with whom they could talk things over comfortably.

Maybe we should be using the People's Doctor Newsletter as a litmus test to help us find more such physicians!