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BEST PILLS

N E W S

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The Same Old Sad Story—Inappropriate Prescribing to the Elderly

“**I**nappropriate medication use is a major patient safety concern, especially for the elderly population.” This is the first sentence of a study published in the December 12, 2001 issue of the *Journal of the American Medical Association*. This study adds to the growing body of research results dating back to 1980 that verifies once again the fact that millions of elderly people are being given dangerous drugs when safer and more effective ones are available.

The authors of the study were from the Agency for Healthcare Research and Quality, part of the U.S. Department of Health and Human Services, Johns Hopkins University, and the University of Rochester. Among the objectives of the study was to determine the prevalence of potentially inappropriate prescribing involving older adults living in the

community (i.e., not in institutions) in 1996. A list of 33 inappropriate drugs, developed by a seven member expert panel, was used for the study.

The drugs were classified in three categories: drugs that (1) should always be avoided, (2) are rarely appropriate, and (3) have some valid uses but are often mis-prescribed in the elderly. The authors used the latest available national estimates from the 1996 Medical Expenditure Panel Survey (MEPS), a nationally representative survey of health care use, including drug use, for prescribing information to determine the prevalence of inappropriate prescribing.

In 1996, 21.3 percent of older adults living in the community received at least one of these potentially inappropriate drugs. Using the

three classifications determined by the expert panel about 2.6 percent of elderly patients used at least one of the 11 drugs that should always be avoided by the elderly. Over 9 percent of elderly patients used at least one of the eight drugs that are considered rarely appropriate. For the 14 drugs the expert panel classified as having some use in elderly patients but were often misprescribed, 13.3 percent of patients received at least one of these drugs.

The three tables below list the 33 drugs according to three categories defined by the expert panel. Also, in the right hand column are our recommendations for the use of these drugs from the first edition of *Worst Pills, Best Pills* published in 1988 unless otherwise noted.

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Table 1—Expert Panel’s “Always Avoid” Drugs Compared to 1988 Recommendations in *Worst Pills, Best Pills*

Generic Name	Brand Name(s)	Worst Pills, Best Pills Recommendation
barbiturates	BUTISOL, NEMBUTAL, SECONAL	Do Not Use
belladonna alkaloids	(ingredient in DONNATAL)	Do Not Use
chlorpropamide	DIABINESE	Do Not Use
dicyclomine	BENTYL	Do Not Use
flurazepam	DALMANE	Do Not Use
hyoscyamine	(ingredient in DONNATAL)	Do Not Use
meperidine	DEMEROL	OK to Use
meprobamate	EQUANIL, MILTOWN	Do Not Use
pentazocine	TALWIN	Do Not Use
propranolol	PRO-BANTHINE	Not Evaluated
trimethobenzamide	TIGAN	Do Not Use

Table 2—Expert Panel’s “Rarely Appropriate” Drugs Compared to 1988 Recommendations in *Worst Pills, Best Pills*

Generic Name	Brand Name(s)	Worst Pills, Best Pills Recommendation
carisoprodol	SOMA	Do Not Use
chlordiazepoxide	LIBRIUM	Do Not Use
chlorzoxazone	PARAFON FORTE DSC	Do Not Use
cyclobenzaprine	FLEXERIL	Do Not Use
diazepam	VALIUM	Do Not Use
metaxalone	SKELAXIN	Not Evaluated
methocarbamol	ROBAXIN	Do Not Use
propoxyphene	DARVON	Do Not Use

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Overall, we had listed 64.6 percent, 21 of the 33 drugs, as *Do Not Use*. For the drugs that the expert panel recommended to Always Avoid, Table 1, we listed 82

percent, 9 of the 11, as *Do Not Use* drugs. We disagreed with the expert panel on meperidine (DEMEROL), a narcotic painkiller, and we have not evaluated propranolol (PRO-BANTHINE), though we do not disagree with the expert panel’s

recommendation on this drug.

Table 2 lists the drugs the expert panel classified as Rarely Appropriate, of these eight drugs, we listed seven, or 88 percent, as *Do Not Use*. The exception is the drug

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meperidine	10	NORMODYNE	14	progestogens	15	SKELAXIN	10
meprobamate	10	NORPACE	11	promethazine	11	SOMA	10
metaxalone	10	olanzapine	13	PROMETRIUM	15	TALWIN	10
methocarbamol	10	oxybutynin	11	propranolol	10	terbinafine	14
methylidopa	11	PARAFON FORTE DSC	10	propoxyphene	10	TICLID	11
MILTOWN	10	pentazocine	10	PROVERA	15	ticlopidine	11
nefazodone	12	PERIACTIN	11	reserpine	11	TIGAN	10
NEMBUTAL	10	PERSANTINE	11	ROBAXIN	10	TRANDATE	14
norethindrone	15	PHENERGAN	11	SECONAL	10	trimethobenzamide	10
norethisterone	15	PRO-BANTHINE	10	SERZONE	12	VALIUM	10
		progesterone	15	SINEQUAN	11	VISTARIL	11
						ZYPREXA	13

Table 3—Expert Panel’s “Some Indications (Uses)” Drugs in the Elderly Compared to 1988 Recommendations in *Worst Pills, Best Pills*

Generic Name	Brand Name(s)	<i>Worst Pills, Best Pills</i> Recommendation
amitriptyline	ELAVIL	Do Not Use
chlorpheniramine	CHLOR-TRIMETON	OK to Use
cyproheptadine	PERIACTIN	OK to Use
diphenhydramine	BENADRYL	OK to Use
dipyridamole	PERSANTINE	Do Not Use
disopyramide	NORPACE	OK to Use
doxepin	SINEQUAN	Limited Use
hydroxyzine	ATARAX, VISTARIL	OK to Use
indomethacin	INDOCIN	Do Not Use
methyl dopa	ALDOMET	Do Not Use
oxybutynin	DITROPAN	Limited Use
promethazine	PHENERGAN	Limited Use
reserpine		Do Not Use
ticlopidine	TICLID	Last Choice—1999 edition

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metaxalone (SKELAXIN), a muscle relaxant, that we have not evaluated.

The expert panel listed 14 drugs as having Some Indications, or uses, in the elderly in Table 3. Of these, we listed five (36 percent) as *Do Not Use* in *Worst Pills, Best Pills*. Another three of these drugs are listed as Limited Use and one as a Last Choice drug. All the other five drugs had boxed warnings in the FDA-approved labeling and, in *Worst Pills, Best Pills* we wrote about adverse reactions, especially directed at older adults. Limited Use drugs are those that published studies indicate should only be used as a “second-line” (alternative) drug if another drug does not work, or the evidence shows that it is more dangerous than another drug but not so much so that it merits being listed as *Do Not Use*.

The authors estimate that in 1996 almost one million elderly patients living in the community received at least 1 of the 11 drugs that the expert panel classified as Always Avoid. This is an alarming number

that we think is a gross underestimate of the extent of inappropriate prescribing to the elderly. The authors point out that they did not assess drug-disease interactions, drug-drug interactions, and drug administration-related problems, such as too high a dose of a drug for an older patient. They also note that given the rate of introduction of new drugs on the market that are rarely studied in the elderly that it is likely that recently released drugs may be potentially inappropriate for use in elderly patients. Of course we agree with this statement; that is one reason why we research and write *Worst Pills, Best Pills News*.

There is another reason we believe that this study represents only a fraction of inappropriate prescribing in the elderly. This list of potentially inappropriate drugs only contained 33 products. In the 1988 edition of *Worst Pills, Best Pills*, we listed 104 drugs as *Do Not Use*, by the 1993 edition this number had increased to 116, and then skyrocketed to 160 in the most recent edition of the book. We are in the process of preparing a supplement to the book that should be ready

this spring that reviews drugs approved since the last edition. This supplement contains at least 20 more drugs that will be listed as *Do Not Use*.

The majority of the 33 drugs in this study have been on the market for years and are not heavily promoted to health professionals or directly to consumers. Why then are they still being prescribed? Years ago, these drugs were heavily advertised and the use of these products became ingrained in the prescribing practice of many physicians. A lot of new physician’s prescribing habits are picked up on the job from older colleagues. The editorial that accompanied this study summed up the situation by saying “Their [the 33 drugs] continuing use is testimony to the triumph of habit over evidence in shaping drug prescribing choices.” We agree.

What You Can Do

Your best chance of avoiding drug-induced death or illness is to read *Worst Pills, Best Pills News* and the book *Worst Pills, Best Pills*.

Do Not Use!

Life-threatening Liver Toxicity with the Antidepressant Nefazodone (SERZONE)

The Food and Drug Administration (FDA) informed pharmaceutical giant Bristol-Myers Squibb Co. on December 10, 2001 that it must add a black box warning to the professional product label, or “package insert,” for the antidepressant nefazodone (SERZONE), informing doctors and pharmacists that life-threatening liver damage can occur with this drug. A black box warning is the strongest type of warning that the FDA can require on a drug’s label. This action follows a warning issued by Canadian government authorities earlier this summer.

The risk of liver failure with nefazodone use appears to be about three to four times the estimated background rate of liver disease, which is likely an underestimate because of the extent of under-reporting of adverse drug reactions. The FDA estimates that only 1 in 10 serious reactions are ever reported to the agency. Therefore, the true rate of liver failure with this drug is probably considerably greater.

Nefazodone was cleared for marketing in December 1994. In 2000, there were over 4.5 million nefazodone prescriptions dispensed in the U.S.

A July 2000 change in nefazodone’s professional product labeling was buried in this fine print reference to the drug’s association with liver toxicity: “Rare reports of liver necrosis [liver cell death] and liver failure, in some cases leading to liver transplantation and/or death.”

Liver failure resulting in death or liver transplant occurred from two weeks to six months after starting nefazodone. Some reports described

patients experiencing early, non-specific symptoms of liver toxicity such as loss of appetite, malaise, and gastrointestinal symptoms. However, other reports did not indicate that patients had experienced the early symptoms of toxicity.

The full text of the new boxed warning follows:

WARNING

Cases of life-threatening hepatic failure have been reported in patients treated with SERZONE. The reported rate in the United States is about 1 case of liver failure resulting in death or transplant per 250,000—300,000 patient-years of SERZONE treatment. The total patient-years is a summation of each patient’s duration of exposure expressed in years. For example, one patient-year is equal to two patients each treated for six months, three patients each treated for four months, etc.

Ordinarily, treatment with SERZONE should not be initiated in individuals with active liver disease or with elevated baseline serum transaminases. There is no evidence that pre-existing liver disease increases the likelihood of developing liver failure, however, baseline abnormalities can complicate patient monitoring.

Patients should be advised to be alert for signs and symptoms of liver dysfunction (jaundice, anorexia, gastrointestinal complaints, malaise, etc.) and to report them to their doctor immediately if they occur.

SERZONE should be discontinued if clinical signs or symptoms suggest liver failure. Patients who develop evidence of hepatocellular injury such as increased serum AST or serum ALT levels three times the upper limit of NORMAL, while on SERZONE should be with-

drawn from the drug. These patients should be presumed to be at increased risk for liver injury if SERZONE is reintroduced. Accordingly, such patients should not be considered for re-treatment.

Nefazodone’s new labeling also contains a chilling statement about using blood tests to monitor for liver toxicity by measuring the levels of liver enzymes: “Periodic serum transaminase [liver enzymes] testing has not been proven to prevent serious injury but it is generally believed that early detection of drug-induced hepatic injury along with immediate withdrawal of the suspect drug enhances the likelihood for recovery.”

There are currently two dozen antidepressants, in at least four pharmacologic classes, available on the market in the U.S. Not one of these drugs has been shown to be superior to another in the treatment of depression in controlled clinical trials. The best way to differentiate one from another, as is the case with most families of drugs which have similar efficacy, is on the basis of their known toxicities. Clearly, nefazodone possesses a known significant toxicity, the possibility of liver failure and death.

What You Can Do

If you have never before been treated with an antidepressant, there is no medical reason why you should be started on nefazodone.

If you are currently taking nefazodone, discuss with your doctor switching to one of the numerous other, safer antidepressant drugs on the market.

New Adverse Drug Reaction: Elevated Blood Sugar from New Antipsychotic Drugs in Adolescents

Medical officers from the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, along with a physician from the Duke University Medical Center, have reported a possible link between the use of the new antipsychotic drugs clozapine (CLOZARIL) and olanzapine (ZYPREXA) in adolescents and elevations in blood sugar levels (hyperglycemia) in 20 of these children. The report was published as a letter to the editor in the November 28, 2001 issue of the *Journal of the American Medical Association*.

Exactly how these drugs cause elevated blood sugar levels is unknown.

These drugs are referred to as "atypical antipsychotics." All antipsychotic drugs usually improve symptoms such as agitation, delusions, hallucinations, and suspiciousness. Atypical antipsychotics additionally tend to improve negative symptoms such as apathy, disorientation, emotional

withdrawal, and lack of pleasure, more than the older antipsychotics. However, there is no clear evidence that they are more effective or better tolerated than the conventional antipsychotics.

The authors of the letter searched the FDA's adverse drug reaction data base to identify cases of hyperglycemia in patients younger than 19 years of age.

Between January 1996 and May 2001, the FDA received nine reports of hyperglycemia associated with the use of olanzapine in four males and five females aged 13 to 18. In seven of these cases, the hyperglycemia was newly diagnosed and in two instances there was worsening of preexisting diabetes. Elevated blood sugar levels appeared within one week after starting olanzapine in two cases and within six months in six other cases. Control of blood sugar levels improved in four patients after the drug was stopped or the dosage decreased. However, in one case, the hyperglycemia recurred after the patient was

switched to other drugs. In this group of patients there was one death from inflammation of the pancreas (pancreatitis).

The FDA also received reports of hyperglycemia in seven males and four females, all between 13 and 18, associated with the use of clozapine between January 1993 and March 2001. Hyperglycemia was newly diagnosed in eight of these children and two experienced worsening of existing diabetes. Hyperglycemia occurred within six weeks of starting clozapine in five children and within six months for five others. The drug was discontinued or the dosage lowered in six, and blood sugar control improved in three of the children.

In these 20 children, two also experienced pancreatitis, though one was also taking a drug known to cause this condition. Again, because pancreatitis is uncommon in children, this suggests a causal association with the use of olanzapine and clozapine. In

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Important Drug Warning!

Dispensing Errors Continue With Lamotrigine (LAMICTAL)

In the August 2000 issue of *Worst Pills, Best Pills News* we wrote about reports of dispensing errors involving the drugs lamotrigine (LAMICTAL) and terbinafine (LAMISIL). Lamotrigine is approved by the Food and Drug Administration (FDA) for certain types of seizure disorders and terbinafine for the treatment of toenail and fingernail fungal infections.

On December 7, 2001 Lamictal's manufacturer, GlaxoSmithKline, issued another warning about dispensing errors involving substitution of their drug with four other drugs. In addition to Lamisil, errors have been reported with the AIDS drug lamivudine (EPIVIR), maprotiline (LUDIOMIL), an antidepressant, labetalol (NORMODYNE, TRANDATE) used for high blood pressure, and diphenoxylate and atropine (LOMOTIL), an old and dangerous anti-diarrhea drug.

Patients with seizure disorders who do not receive their antiepileptic drug lamotrigine due to a dispensing error would be inadequately treated and could experience serious consequences including continuous seizures (status epilepticus). Conversely,

*Always check
the tablets before
you leave the
pharmacy*

patients mistakenly given Lamictal instead of one of the drugs listed above would be unnecessarily subjected to a risk of potential adverse effects. This is especially true if patients receive a high initial dose of Lamictal.

The professional product labeling or "package insert" for lamotrigine carries, in part, the following bold-faced, boxed warning regarding skin reactions including a potentially life-threatening reaction called "toxic epidermal necrolysis," in which the skin sloughs off:

SERIOUS RASHES REQUIRING HOSPITALIZATION AND DISCONTINUATION OF TREATMENT HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF LAMICTAL. THE INCIDENCE OF

THESE RASHES WHICH HAVE INCLUDED STEVENS-JOHNSON SYNDROME IS APPROXIMATELY 1% (1/100) IN PEDIATRIC PATIENTS (AGE <16 YEARS) AND 0.3% (3/1000) IN ADULTS. IN WORLDWIDE POSTMARKETING EXPERIENCE, RARE CASES OF TOXIC EPIDERMAL NECROLYSIS AND/OR RASH-RELATED DEATH HAVE BEEN REPORTED, BUT THEIR NUMBERS ARE TOO FEW TO PERMIT A PRECISE ESTIMATE OF THE RATE.

Lamictal is marketed as 25, 100, 150, and 200 milligram six-sided, shield-shaped tablets bearing "Lamictal" and the numeric representation of the strength (e.g., "Lamictal 150"). Lamictal Chewable Dispersible Tablets are 5 milligram, and 25 milligram white tablets engraved with "GX CL2" and "GX CL5," respectively.

What You Can Do

If you are taking lamotrigine, always check the tablets before you leave the pharmacy and verify by reading on the tablets the words LAMICTAL.

If you are taking one of the other drugs mentioned above, always check before you leave the pharmacy and verify that the tablets *do not* have LAMICTAL imprinted on them.

If you become aware of a prescription-dispensing error involving these or any other products it should be reported to the FDA MEDWATCH program by phone 1-800-FDA-1088, by FAX 1-800-FDA-0178, by internet www.fda.gov/medwatch, or by mail: MedWatch HF-2, FDA, 5600 Fishers Lane Rockville, MD 20857.

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addition, the two cases of pancreatitis were found in the search for hyperglycemia and may not represent all cases of pancreatitis in the FDA's database.

In general, the newer atypical antipsychotics should not be considered as first choices for the treatment of severe mental illness in

children and adolescents.

What You Can Do

If your child is taking olanzapine or clozapine, since there are no approved guidelines for monitoring blood sugar with these drugs, you should discuss with your child's physician the possibility of routine monitoring for hyperglycemia.

No Evidence To Support the Use of Progesterone in the Management of Premenstrual Syndrome (PMS)

Researchers from the United Kingdom reported in the October 6, 2001 issue of the *British Medical Journal* that published medical evidence does not support the use of progesterone in the treatment of premenstrual syndrome (PMS) and that it is unlikely that progestogens are effective in this disorder.

Progesterone is a naturally occurring hormone produced in women's bodies and progestogens are synthetic variations of progesterone. The progestogens medroxyprogesterone (PROVERA) and norethisterone known in the U.S. as norethindrone (AYGESTIN), both marketed in this country, and dydrogesterone, an agent not available in the U.S., were included in the research.

There are several Food and Drug Administration regulated progesterone products on the market. Examples are PROMETRIUM capsules and CRINONE, a vaginal gel preparation. None of the progesterone or progestogen products are approved for the treatment of PMS. When these drugs are prescribed for PMS it is being done without proof that they are effective or safe for this use. Prescribing drugs in this manner is referred to as "off-label" prescribing. No laws or regulations exist that prevent physicians from prescribing drugs for off-label uses and there is no requirement that patients be informed that they are receiving a drug for what amounts to an experimental use.

The U.K. study is a meta-analysis, which is a statistical summary of clinical trials. The researchers identified clinical trials involving the use of progesterone or progestogens in the management of PMS. Those clinical trials that met a

predefined quality standard were included in the meta-analysis. There were 10 trials of progesterone treatment in 531 women and four trials of progestogen use in 378 women with PMS that were deemed of sufficient quality to be included in the study.

The main outcome measure the researchers evaluated was the proportion of women whose PMS symptoms showed improvement with progesterone or progestogen preparations. For progesterone preparations, either oral or suppositories, no clinically important difference was found between this drug and placebo. In the progestogen trials there was a statistically positive finding, but not a clinically significant improvement in symptoms for women using a progestogen.

In the absence of large randomized controlled clinical trials, the scientific "gold standard," meta-analyses offer the best evidence of the therapeutic value of a treatment. One disadvantage of meta-analyses based only on published studies is that published clinical trials tend to be those with a positive result, in this case a positive effect for progesterone or progestogen. This is known as publication bias which can lead to an overestimation of the benefit of a treatment.

The authors of the study included a very interesting discussion of the rationale for use of progesterone or progestogens in PMS. The use of these drugs is based on the unsubstantiated premise that progesterone deficiency is the cause of PMS. The authors point out that initial studies suggested there were abnormal concentrations of the breakdown products of progesterone; however there is no consistent evidence that

low concentrations of this hormone are found in women with PMS.

The off-label use of progesterone and progestogens in PMS illustrates a frequent error on the part of those who view the human body as a simple machine. The ability of biochemists and other scientists to identify chemical reactions and measure levels of naturally occurring chemicals in the body has led to the belief that manipulation of these chemicals is all that is needed for good health. Add a little estrogen to protect the heart after menopause, fine tune serotonin levels to lose weight, or top up with progesterone for PMS are presented as solutions. When the aforementioned practices are carefully studied, it becomes apparent that billions of dollars have been spent on worthless remedies and there is a realization that a lot of people needlessly suffered adverse drug reactions from these treatments.

Progesterone and progestogens are significantly associated with serious drug reactions. These include blood-clotting disorders that can lead to clots in the legs, stroke, and blindness. Also, there is an increased risk of minor birth defects in children whose mothers take these drugs during the first four months of pregnancy. Several reports suggest an association between mothers who take these drugs in the first trimester of pregnancy and genital abnormalities in male and female babies.

What You Can Do

You should avoid the use of progesterone and progestogens to manage the symptoms of PMS. The best evidence does not support their use in PMS.

Canadians Begin Recall of Dangerous Drug Supplement Ephedra

On January 9, 2002, Canadian regulatory authorities announced the initiation of a voluntary recall of certain products containing the drug supplement Ephedra and one of its pure chemical constituents, ephedrine. Ephedra and ephedrine are mostly found in dietary supplements promoted for weight loss and energy enhancement. If voluntary compliance with the recall is not achieved, the option for stronger regulatory action, including the seizure of violative products, was left open.

Public Citizen's Health Research Group has already filed a petition to the Food and Drug Administration to ban all ephedrine-containing dietary supplements. You can access the petition at www.citizen.org/publications/release.cfm?ID=7053 or by writing to us for a copy at Health Research Group, 1600 20th Street, NW, Washington, DC 20009.

The Canadian decision was reached after a risk assessment concluded that these products pose a serious health risk. Adverse events including stroke, heart attacks, heart rate irregularities, seizures, psycho-

You should not use Ephedra or ephedrine-containing drugs.

ses and deaths have been reported in association with the use of some products containing Ephedra or ephedrine.

This recall deals with the following types of Ephedra or ephedrine products:

1. Products having a dose of more than 8 milligrams of ephedrine or with a label recommending more than 8 milligrams per dose or 32 milligrams per day and/or are labeled or implied for use exceeding seven days.
2. All combination products containing Ephedra or ephedrine together with another stimulant

such as caffeine and other ingredients which might increase the effect of Ephedra or ephedrine in the body.

3. Products with labeled or implied claims for appetite suppression, weight loss promotion, metabolic enhancement, increased exercise tolerance, body-building effects, increased energy or wakefulness, or other stimulant effects.

This action by the Canadian authorities is a rational regulatory policy to protect their citizens from dangerous drug supplements. In this country, the public must face alone the irrationality of an unregulated market for drug supplements because of the Dietary Supplement Health and Education Act enacted in 1994.

What You Can Do

You should not use Ephedra or ephedrine-containing drugs. They are dangerous and without a legitimate medical use.

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