

# Letters to the Editor

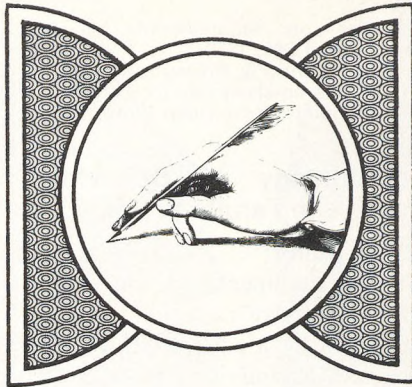
The Journal welcomes Letters to the Editor; if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.

## Effectiveness of Appointment Reminders

To the Editor:

We enjoyed Dr. Hagerman's article, "Testing the Mailed Appointment Reminder in Family Practice" (*J Fam Pract* 7:199, 1978). He rightly points out that all previous studies on the subject examined only outpatient clinics. This article is an excellent contribution using a model family practice unit. We would like to comment further on his findings.

Dr. Hagerman analyzes data using appointments made one week in advance. We agree that there is a relation between how much in advance an appointment is made and the rate of failed appointments. Gates and Colborn show that patients scheduled three to four weeks in advance had a fail rate of 35 percent compared to 20 percent in their population as a whole.<sup>1</sup> Another study showed that appointments made four to five weeks in advance had a fail rate of 67 percent compared to 44 to 50 percent for those made 12 to 28 days in advance.<sup>2</sup> Hofmann and Rockart reported that only 26 percent of a control group's appointments were made more than two months in advance, but that 35 percent of the group who failed had appointments scheduled more than two months in advance.<sup>3</sup> We believe that remind-



ers sent to those with appointments one to two weeks in advance may not reflect those most at risk for failed appointments and, thus, most likely to benefit from a reminder system.

We would be interested to know whether Dr. Hagerman has analyzed data with appointments made two to three weeks in advance.

*Gene L. Oppenheim, MD, MPH  
James J. Bergman, MD  
Eugenia C. English, MD  
Department of Family Medicine  
University of Washington  
Seattle*

## References

1. Gates SJ, Colborn DK: Lowering appointment failures in a neighborhood health center. *Med Care* 14:263, 1976
2. Nazarian LF, Mechaber J, Charney E, et al: Effect of a mailed appointment reminder on appointment keeping. *Pediatrics* 53:349, 1974
3. Hofmann PB, Rockart JF: Implications of the no-show rate for scheduling OPD appointments. *Hosp Prog* 50:35, 1969

*The preceding letter was referred to Dr. Hagerman who responds as follows:*

I appreciated the letter from Drs. Oppenheim, Bergman, and English of the Department of Family Medicine at the University of Washington.

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**Mavalox**  
before, during and after  
any ulcer regimen...  
WILLIAM H. RORER, INC., Fort Washington Pa. 19034

Continued from preceding page

In my study, "Testing the Mailed Appointment Reminder in Family Practice" (*Hagerman GA: J Fam Pract 7:199, 1978*) one control group consisted of 446 appointments booked anywhere from one week to months in advance of their actual appointment date. This group was found to significantly fail their appointments more often than a similar control group of 1,127 appointments which were all booked less than a week in advance. The "no-show" rate of this former group, as a whole, was not seen to be significantly affected by a mailed appointment reminder. Unfortunately, this study cannot provide any further information on the failure rates of appointments booked at various intervals in advance. Others such as Gates and Colburn<sup>1</sup> using outpatient settings felt "compliance was not found to be associated with . . . the number of weeks in advance that the appointment was scheduled." However, as pointed out, workers like Nazarian<sup>2</sup> and Hofmann<sup>3</sup> hold views to the contrary, again using outpatient clinic data.

It is indicative that further testing of the mailed appointment reminder in family practice is required.

Gordon A. Hagerman, MD  
USC-Los Angeles County  
Medical Center  
Department of  
Emergency Medicine  
Los Angeles, California  
Formerly of McMaster University  
Henderson Family Practice Center  
Hamilton, Ontario

#### References

1. Gates SJ, Colburn DK: Lowering appointment failures in a neighborhood health center. *Med Care 14:263, 1976*
2. Nazarian LF, Mechaber J, Charney E, et al: Effect of a mailed appointment

reminder on appointment keeping. *Pediatrics 53:349, 1974*

3. Hofmann PB, Rockart JF: Implications of the no-show rate for scheduling OPD appointments. *Hosp Prog 50:35, 1969*

## Terminology of Behavioral Science in Family Practice

To the Editor:

These comments are concerning Dr. Brockway's recent article, "Behavioral Medicine in Family Practice: A Unifying Approach for the Assessment and Treatment of Psychosocial Problems" (*J Fam Pract 6:545, 1978*). We would like to indicate at the outset that the article was excellent in concept and we are totally in agreement with the appropriateness and efficacy of the techniques she describes for use in family medicine. We must take issue with the use of the term *behavioral medicine*, however, for several reasons which amount to more than semantic squabbling.

First, the term has a danger of implying that these techniques are "medicine for behavior." They are not. They are techniques from behavioral psychology (behavior modification and, more generally, behavior therapy) which are applied to behaviors relevant to medical concerns. This distinction is highlighted by the fact that Williams and Gentry chose to title their recent volume, which is most representative of this area, *Behavioral Approaches to Medical Treatment*<sup>1</sup> rather than an alternate term (reviewed in the same issue of *The Journal of Family Practice 6:678, 1978*).

Further, while it is alluded to in the article, it must be *strenuously* emphasized that behavioral medicine is not an accepted term for the limited scope defined by Dr. Brockway. Behavioral medicine in

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Brief Summary of Prescribing Information  
Benylin® Cough Syrup

Each 5 ml contains:

Benadryl® (diphenhydramine hydrochloride) . . . . . 12.5mg  
Alcohol . . . . . 5%

Also contains, as inactive ingredients, sugar, water, glucose, liquid, glycerin, ammonium chloride; sodium citrate; raspberry imitation flavor; sodium saccharin; citric acid; caramel; menthol; FD&C Red 40; and D&C Red 33.

**INDICATIONS.** Benylin Cough Syrup is indicated as an antitussive for the control of cough due to colds or allergy.

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified this indication as follows:

There is a lack of substantial evidence that this fixed combination drug has the effect purported. Final classification of the less-than-effective indication requires further investigation.

**CONTRAINDICATIONS.** Use in Newborn or Premature Infants: This drug should not be used in newborn or premature infants.

**Use in Nursing Mothers:** Because of the higher risk of antihistamines for infants generally, and for newborns and premature infants in particular, antihistamine therapy is contraindicated in nursing mothers.

**Use in Lower Respiratory Disease:** Antihistamines should NOT be used to treat lower respiratory-tract symptoms including asthma.

Antihistamines are also contraindicated in the following conditions:

Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

Monoamine oxidase inhibitor therapy (See Drug Interaction section).

**WARNINGS.** Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder-neck obstruction, or pyloroduodenal obstruction.

**Use in Children:** In infants and children, especially, antihistamines in *overdosage* may cause hallucinations, convulsions, or death.

As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, antihistamines may produce excitation.

**Use in Pregnancy:** Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

**Use with CNS Depressants:** Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc).

**Use in Activities Requiring Mental Alertness:** Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating appliances, machinery, etc.

**Use in the Elderly (approximately 60 years or older):** Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

**PRECAUTIONS.** Diphenhydramine hydrochloride has an atropine-like action and, therefore, should be used with caution in patients with a history of bronchial asthma, increased intra-ocular pressure, hyperthyroidism, cardiovascular disease, or hypertension.

**DRUG INTERACTIONS.** MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

**ADVERSE REACTIONS.** The most frequent adverse reactions are underscored:

1. *General:* Urticaria; drug rash; anaphylactic shock; photosensitivity; excessive perspiration; chills; dryness of mouth, nose, and throat

2. *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles

3. *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis

4. *Nervous System:* Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresis, thesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions

5. *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation

6. *GU System:* Urinary frequency, difficult urination, urinary retention, early menses

7. *Respiratory System:* Thickening of bronchial secretions; tightness of chest and wheezing, nasal stuffiness

**OVERDOSAGE.** Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms—dry mouth, fixed, dilated pupils; flushing; and gastrointestinal symptoms may also occur.

If vomiting has not occurred spontaneously, the patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children.

If vomiting is unsuccessful, gastric lavage is indicated within three hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic or one-half isotonic saline is the lavage solution of choice. *Saline cathartics*, such as milk of magnesia, draw water into the bowel by osmosis and, therefore, are valuable for their action in rapid dilution of bowel content.

Stimulants should not be used.

Vasopressors may be used to treat hypotension.

**HOW SUPPLIED.** Benylin Cough Syrup is supplied in 4-oz, 1-pt, and 1-gal bottles, and unit-dose bottles of 5 ml and 10 ml.

May 1978

**PARKE-DAVIS**

PARKE-DAVIS  
Division of Warner-Lambert Company  
Morris Plains, NJ 07950

PD-JA-2628-1-C (3-78)

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another article<sup>2</sup> is defined as the confluence of psychosomatics and somatiopsychology involving psychological reactions to organic illness as well as psychological factors in staff and medical personnel, intrapersonally and interprofessionally. Further, the Yale Conference on Behavioral Medicine (February 4-6, 1977) chose to define behavioral medicine more broadly: "Behavioral medicine is the field concerned with the development of behavioral-science knowledge and techniques relevant to the understanding of physical health and illness and the application of this knowledge and these techniques to prevention, diagnosis, treatment and rehabilitation. Psychosis, neurosis, and substance abuse are included only insofar as they contribute to physical disorders as an end point."<sup>3</sup>

The recently published *Journal of Behavioral Medicine* also takes a much broader definition of the field.

Even the Behavioral Medicine Special Interest Group of the Association for the Advancement of Behavior Therapy, which would most likely endorse the definition of behavioral medicine as suggested by Dr. Brockway, is still remaining open to the best term to use to describe efforts in this area.

The importance of this is that the use of the term behavioral medicine in such a limited manner does not recognize the tremendous developmental and organizational changes occurring within the psychological profession to help make psychology more effective in medical settings. These developments include such things as defining the structure of the field, setting up training programs, and consequently assuring maximum quali-

cations for individuals who will teach or provide other psychological services in a medical setting.

Finally, there are brief therapies, applicable to family medicine, which are not necessarily behavioral in nature. The term behavioral medicine requires either exclusion or redefinition in behavioral terms. Therefore, we prefer the term and model of Medical Psychology as a unifying approach which is able to accommodate both behavior modification and behavioral techniques but does not exclude other useful approaches. A paper in this focus can be found in the March issue of *Primary Care*. We would hope that family practice keeps an open mind to the use of these terms just as the psychological profession is doing until that time when formalized structures and guidelines are available. Perhaps contact with the American Psychological Association would also be helpful.

Michael J. Asken, PhD, Director  
and

Arnold T. Shienvold, PhD,  
Assistant Director,  
Behavioral Science and  
Medical Psychology

Departments of Family Practice  
at Harrisburg Hospital and  
Polyclinic Medical Center

and  
Department of Behavioral Science  
Milton S. Hershey Medical Center  
Pennsylvania State University

College of Medicine  
Harrisburg and Hershey,  
Pennsylvania

Bradford K. Strock, MD  
Director

Family Practice  
Residency Program  
Harrisburg Hospital  
Family Practice Center  
Harrisburg, Pennsylvania

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### Brief Summary

**Indication:** Hypertension. (See box warning.)

**Contraindications:** Mental depression, hypersensitivity, and most cases of severe renal or hepatic diseases.

### Warnings:

These fixed combination drugs are not indicated for initial therapy of hypertension. Hypertension requires therapy titrated to the individual patient. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. The treatment of hypertension is not static, but must be reevaluated as conditions in each patient warrant.

Use with caution in patients with severe renal disease, impaired hepatic function or progressive liver disease. Regroton or Demi-Regroton may potentiate action of other antihypertensive, ganglionic and peripheral adrenergic-blocking drugs. Sensitivity reactions may occur in allergic and asthmatic patients. Discontinue one week before electroshock therapy, and if depression or peptic ulcer occurs. **Use in pregnancy:** Thiazides cross the placental barrier and appear in cord blood. The use of chlorthalidone and related drugs in pregnant women requires that the anticipated benefits of the drug be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult. Use with care in nursing mothers since thiazides and reserpine cross the placental barrier and appear in cord blood and breastmilk. Increased respiratory secretions, nasal congestion, cyanosis and anorexia may occur in infants born to reserpine-treated mothers. If use of the drug is essential, the patient should stop nursing. **Precautions:** Antihypertensive therapy with these drugs should always be initiated cautiously in postsympathectomy patients and in patients receiving ganglionic blocking agents, other potent antihypertensive drugs or curare. Reduce dosage of concomitant antihypertensive agents by at least one-half. To avoid hypotension during surgery, discontinue therapy with these agents two weeks prior to elective surgical procedures. In emergency surgery, use anticholinergic or adrenergic drugs or other supportive measures if needed. Because of the possibility of progression of renal damage, periodic kidney function tests are indicated. Discontinue if the BUN rises or liver dysfunction is aggravated (hepatic coma may be precipitated). Patients receiving chlorthalidone should have periodic determination of serum electrolytes and should be observed for clinical signs of fluid or electrolyte imbalance (hyponatremia, hypochloremic alkalosis and hypokalemia), particularly if they are receiving digitalis, parenteral fluids, or are vomiting excessively. Hypokalemia may develop with chlorthalidone as with any other potent diuretic, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Digitalis therapy may exaggerate metabolic effects of hypokalemia especially with reference to myocardial activity. Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather. Hyperuricemia may occur or gout be precipitated in certain patients. Insulin requirements in diabetic patients may be increased, decreased, or unchanged and latent diabetes mellitus may become manifest. Chlorthalidone and related drugs may decrease arterial responsiveness to norepinephrine. Chlorthalidone and related drugs may decrease serum PBI levels without signs of thyroid disturbance. Use cautiously in patients with ulcerative colitis or gallstones (biliary colic may be precipitated). Bronchial asthma may occur in susceptible patients. **Adverse Reactions:** These drugs are generally well tolerated. The most frequent adverse reactions are anorexia, nausea, vomiting, gastric irritation, diarrhea, constipation, headache, dizziness, weakness, muscle cramps, nasal congestion, drowsiness and mental depression. Other potential side effects include skin rash, urticaria, ecchymosis; hyperglycemia and glycosuria (diabetics should be checked regularly), hyperuricemia and acute gout, and impotence. With chlorthalidone: restlessness, transient myopia; dysuria, orthostatic hypotension (may be potentiated by alcohol, barbiturates or narcotics), rare idiosyncratic reactions such as aplastic anemia, leukopenia, thrombocytopenia, agranulocytosis, purpura, necrotizing angitis and Lyell's syndrome (toxic epidermal necrolysis); pancreatitis when epigastric pain or unexplained G.I. symptoms develop after prolonged

Continued on facing page.

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## References

1. Williams RB Jr, Gentry WD: Behavioral Approaches to Medical Treatment. Cambridge, Mass, Ballinger, 1977
2. Asken MJ: Medical psychology: Towards definition, clarification, and organization. Profess Psychol, in press, 1978
3. Behavioral Medicine Newsletter. February, 1978. Association for the Advancement of Behavior Therapy, Department of Psychology, State University of New York at Oswego, NY

## Diagnostic X-Rays for Low Back Pain

To the Editor:

Have just read the September issue of *The Journal*. As a long-time, if inactive member of the Society of Teachers of Family Medicine, but perhaps one of its first osteopathic physicians in full-time academics, I feel obliged to respond to what appear to be some quite serious methodologic errors contained in the article by Rockey et al, assessing the usefulness of x-ray examinations in the evaluation of patients with back pain.

Undergraduate osteopathic students, most of whom are headed for primary care careers, will spend a minimum of 300 classroom hours learning to cope, both diagnostically and therapeutically, with neuromuscular disorders, the majority of which are related to "non-pathologic" movement disorders, eg, lumbosacral strain secondary to sidebending rotation stress and frequently accompanied by facet joint asymmetry with or without sacroiliac joint rotation. When looked for, these are easily discerned in a radiograph.

My concern is that the conclusions in the article fail completely to mention this reality and focus heavily on a disease-oriented algorithm.

I am not taking issue with a "let's always look for the worst possible cause" philosophy; it has great merit. I do register major

concern, however, when (as documented in Table 1, Distribution of Diagnoses) a 64-percent failure rate in diagnosis leads to a conclusion that x-ray examinations have a low cost-benefit ratio.

I know of no other area in medicine where such low diagnostic accuracy is allowed to go unchallenged.

After 25 years of work as a family physician, and particularly one who by virtue of interest, research concern, and osteopathic background has been able to document causes of low back pain physiologically and clinically with an accuracy in excess of 95 percent, I am concerned that inappropriate conclusions are deduced from an inadequate data base. As noted in recent articles in *Patient Care* magazine outlining algorithms to analyze low back pain, the standing AP and lateral x-rays of the lumbar spine are among the most productive procedures to develop a good management plan.<sup>1-3</sup>

Robert C. Ward, DO, FFAO

Professor

Family Medicine

Medical Education Research and

Development

Michigan State University

College of Osteopathic Medicine

East Lansing

## References

1. Why go fishing for back pain causes? *Patient Care* 10(10):126, 1976
2. Keys to treating acute back or neck pain. *Patient Care* 10(15):18, 1976
3. When back/neck pain hangs on and on. *Patient Care* 11(3):58, 1977

The preceding letter was referred to Dr. Rockey who responds as follows:

Dr. Ward, aided by low back x-rays, claims exceptional acumen in being able to document the cause of low back pain in greater than 95 percent of the cases. Lawyers have

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**FOR DEEP INTRAMUSCULAR INJECTION ONLY.**  
**Indications:** In treatment of infections due to penicillin G-sensitive microorganisms susceptible to the low and very prolonged serum levels common to this dosage form. Therapy should be guided by bacteriological studies (including sensitivity tests) and clinical response.

The following infections usually respond to adequate dosage of IM penicillin G benzathine.  
**Streptococcal infections** (Group A—without bacteremia). Mild to moderate upper respiratory infections (e.g., pharyngitis).

**Venereal infections**—Syphilis, yaws, bejel, and pinta.

Medical conditions in which penicillin G benzathine therapy is indicated as prophylaxis:

**Rheumatic fever and/or chorea**—Prophylaxis with penicillin G benzathine has proven effective in preventing recurrence of these conditions. It has also been used as followup prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.

**Contraindications:** Previous hypersensitivity reaction to any penicillin.

**Warnings:** Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported. Anaphylaxis is more frequent following parenteral therapy but has occurred with oral penicillins. These reactions are more apt to occur in individuals with history of sensitivity to multiple allergens. Severe hypersensitivity reactions with cephalosporins have been well documented in patients with history of penicillin hypersensitivity. Before penicillin therapy, carefully inquire into previous hypersensitivity to penicillins, cephalosporins and other allergens. If allergic reaction occurs, discontinue drug and treat with usual agents, e.g., pressor amines, antihistamines and corticosteroids.

**Precautions:** Use cautiously in individuals with histories of significant allergies and/or asthma.

Carefully avoid intravenous or intraarterial use, or injection into or near major peripheral nerves or blood vessels, since such injection may produce neurovascular damage.

In streptococcal infections, therapy must be sufficient to eliminate the organism, otherwise the sequelae of streptococcal disease may occur. Take cultures following completion of treatment to determine whether streptococci have been eradicated.

Prolonged use of antibiotics may promote overgrowth of non-susceptible organisms including fungi. Take appropriate measures if superinfection occurs.

**Adverse Reactions:** Hypersensitivity reactions reported are skin eruptions (maculopapular to exfoliative dermatitis), urticaria and other serum sickness-like reactions, laryngeal edema and anaphylaxis. Fever and eosinophilia may frequently be only reaction observed. Hemolytic anemia, leucopenia, thrombocytopenia, neuropathy and nephropathy are infrequent and usually associated with high parenteral doses.

As with other antisyphilitics, Jarisch-Herxheimer reaction has been reported.

**Composition:** (units penicillin G benzathine as active ingredient in aqueous suspension): 300,000 units per ml—10-ml multi-dose vial. Each ml also contains sodium citrate buffer approximately 6 mg lecithin, 3 mg povidone, 1 mg carboxymethylcellulose, 0.5 mg sorbitan monopalmitate, 0.5 mg polyoxyethylene sorbitan monopalmitate, 1.2 mg methylparaben and 0.14 mg propylparaben.

600,000 units in 1-ml TUBEX® (sterile cartridge-needle unit) Wyeth, packages of 10.  
900,000 units, 1.5-ml fill in 2-ml TUBEX, packages of 10.

1,200,000 units in 2-ml TUBEX, packages of 10, and in 2-ml single-dose disposable syringe, packages of 10.

2,400,000 units in 4-ml single-dose disposable syringe, packages of 10.

Each TUBEX or disposable syringe also contains sodium citrate buffer and, as w/v, approximately 0.5% lecithin, 0.6% carboxymethylcellulose, 0.6% povidone, 0.1% methylparaben and 0.01% propylparaben.

INJECTION

**BICILLIN® LA****(STERILE PENICILLIN G BENZATHINE SUSPENSION)**

Wyeth Laboratories Philadelphia, Pa. 19101

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an expression for the line of reasoning he seems to use in his letter: "post hoc, ergo propter hoc," meaning "after this, therefore because of it." This is the logical fallacy of attributing causality to the mere temporal sequence of events. Patients, who may incidentally have asymmetrical facet joints, develop back pain, consult a physician, have an x-ray, and a facet joint asymmetry is found. Ergo, the facet joint asymmetry explains the back pain. How frequently do such findings occur in an age and sex-matched group of persons without back pain? Without such data, obtained in a double-blind manner, it is impossible to know what the diagnostic value of such x-ray findings are. Furthermore, if there is diagnostic value in low back x-rays, does this result in improved patient outcomes sufficient to offset the cost and risk of the procedure? Our data suggest not.

Paul H. Rockey, MD, MPH  
US Public Health Service Hospital  
Seattle, Washington

To the Editor:

Rockey, et al are correct in noting that "The Usefulness of X-Ray Examinations in the Evaluation of Patients with Back Pain" (Rockey PH, Tompkins RK, Wood RW, et al: *J Fam Pract* 7:455, 1978) is minimal in most cases. Evidence from their study and from their review of the literature supports this view. Some caveats appear to be in order, however. First, a radiologist's report of degenerative joint disease is not sufficient for clinical diagnosis, since this radiographic condition is frequently seen in patients free of back symptoms. Secondly, if one does enough x-rays in backache patients, especially those of advancing years, eventually some

serious disease needing early intervention will be discovered. A difficult question of values arises: How important is it, in dollar terms, to make an early diagnosis of the unusual patient with backache due to a severe organic disease? Is there not some point at which good judgment must take precedence over an elusive search for perfection?

As the authors note, it is uncertain whether data from a military medicine setting can be extrapolated to civilian family practice. Possibly backaches are backaches wherever they occur, but the issue must be raised. Are the physical activities of military personnel significantly different from those of civilians, and if so does this lead to a higher or lower incidence of significant back problems? Most of the backaches described in the study were brief; does this suggest that military personnel in good physical condition are less likely to have prolonged backaches than their more sedentary civilian counterparts? Does the secondary gain picture among soldiers (and their dependents) differ from that in civilian life?

Similar questions arise with regard to the measurement of outcomes. Comparison with civilian populations may be difficult since complaining to authority figures is foreign to military tradition. Also, and perhaps more important, patient satisfaction is an imperfect and sometimes duplicitous parameter of quality of care. There are times when it is the physician's duty to make his/her patient unhappy, by refusing to order unneeded studies, by avoiding potentially addicting drugs, or by declining to sign questionable disability certificates.

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## NOVAFED® Capsules

pseudoephedrine hydrochloride  
Controlled-Release Decongestant

**DESCRIPTION:** Each capsule contains 120 mg. of pseudoephedrine hydrochloride in specially formulated pellets designed to provide continuous therapeutic effect for 12 hours. About one half of the active ingredient is released soon after administration and the rest slowly over the remaining time period.

**ACTIONS:** Pseudoephedrine is an orally effective nasal decongestant with peripheral effects similar to epinephrine and central effects similar to, but less intense than, amphetamines. It has the potential for excitatory side effects. At the recommended oral dosage, it has little or no pressor effect in normotensive adults. Patients have not been reported to experience the rebound congestion sometimes experienced with frequent, repeated use of topical decongestants.

**INDICATIONS:** Relief of nasal congestion or eustachian tube congestion. May be given concomitantly with analgesics, antihistamines, expectorants and antibiotics.

**CONTRAINDICATIONS:** Patients with severe hypertension, severe coronary artery disease, and patients on MAO inhibitor therapy. Also contraindicated in patients with hypersensitivity or idiosyncrasy to sympathomimetic amines which may be manifested by insomnia, dizziness, weakness, tremor or arrhythmias.

Children under 12: Should not be used by children under 12 years.

Nursing Mothers: Contraindicated because of the higher than usual risk for infants from sympathomimetic amines.

**WARNINGS:** Use judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism or prostatic hypertrophy. See, however, Contraindications. Sympathomimetics may produce central nervous stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

Do not exceed recommended dosage.

**Use in Pregnancy:** Safety in pregnancy has not been established.

**Use in Elderly:** The elderly (60 years and older) are more likely to have adverse reactions to sympathomimetics. Overdosage of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and death. Safe use of a short-acting sympathomimetic should be demonstrated in the individual elderly patient before considering the use of a sustained-action formulation.

**PRECAUTIONS:** Patients with diabetes, hypertension, cardiovascular disease and hyper-reactivity to ephedrine.

**ADVERSE REACTIONS:** Hyper-reactive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness or nausea. Sympathomimetics have been associated with certain untoward reactions including fear, anxiety, tenseness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias, and cardiovascular collapse with hypotension.

**DRUG INTERACTIONS:** MAO inhibitors and beta adrenergic blockers increase the effects of pseudoephedrine. Sympathomimetics may reduce the antihypertensive effects of methyl-dopa, mecamylamine, reserpine and veratrum alkaloids.

**DOSAGE AND ADMINISTRATION:** One capsule every 12 hours. Do not give to children under 12 years of age.

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

**HOW SUPPLIED:** Brown and orange colored hard gelatin capsules, monogrammed with the Dow diamond followed by the number 104. Bottle of 100 capsules (NDC 0183-0104-02).



DOW PHARMACEUTICALS  
The Dow Chemical Company  
Indianapolis, IN 46268

# BACTRIM™

(trimethoprim and sulfamethoxazole)



Before prescribing, please consult complete product information, a summary of which follows:

**Contraindications:** Hypersensitivity to trimethoprim or sulfonamides; pregnancy; nursing mothers; infants less than two months of age.

**Warnings: BACTRIM SHOULD NOT BE USED TO TREAT STREPTOCOCCAL PHARYNGITIS.** Clinical studies show that patients with group A  $\beta$ -hemolytic streptococcal tonsillopharyngitis have higher incidence of bacteriologic failure when treated with Bactrim than do those treated with penicillin. Deaths from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias have been associated with sulfonamides. Experience with trimethoprim is much more limited but occasional interference with hematopoiesis has been reported as well as an increased incidence of thrombopenia with purpura in elderly patients on certain diuretics, primarily thiazides. Sore throat, fever, pallor, purpura or jaundice may be early signs of serious blood disorders. Frequent CBC's are recommended; therapy should be discontinued if a significantly reduced count of any formed blood element is noted.

**Precautions:** Use cautiously in patients with impaired renal or hepatic function, possible folate deficiency, severe allergy or bronchial asthma. In patients with glucose-6-phosphate dehydrogenase deficiency, hemolysis, frequently dose-related, may occur. During therapy, maintain adequate fluid intake and perform frequent urinalyses, with careful microscopic examination, and renal function tests, particularly where there is impaired renal function. Bactrim may prolong prothrombin time in those receiving warfarin; reassess coagulation time when administering Bactrim to these patients.

**Adverse Reactions:** All major reactions to sulfonamides and trimethoprim are included, even if not reported with Bactrim. *Blood dyscrasias:* Agranulocytosis, aplastic anemia, megaloblastic anemia, thrombopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia. *Allergic reactions:* Erythema multiforme, Stevens-Johnson syndrome, generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis. *Gastrointestinal reactions:* Glossitis, stomatitis, nausea, emesis, abdominal pains, hepatitis, diarrhea and pancreatitis. *CNS reactions:* Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo, insomnia, apathy, fatigue, muscle weakness and nervousness. *Miscellaneous reactions:* Drug fever, chills, toxic nephrosis with oliguria and anuria, periarteritis nodosa and L.E. phenomenon. Due to certain chemical similarities to some goitrogens, diuretics (acetazolamide, thiazides) and oral hypoglycemic agents, sulfonamides have caused rare instances of goiter production, diuresis and hypoglycemia in patients; cross-sensitivity with these agents may exist. In rats, long-term therapy with sulfonamides has produced thyroid malignancies.

**Dosage: Not recommended for infants less than two months of age.**  
**URINARY TRACT INFECTIONS AND SHIGELLOSIS IN ADULTS AND CHILDREN, AND ACUTE OTITIS MEDIA IN CHILDREN:**

**Adults:** Usual adult dosage for urinary tract infections—1 DS tablet (double strength), 2 tablets (single strength) or 4 teasp. (20 ml) b.i.d. for 10-14 days. Use identical daily dosage for 5 days for shigellosis.

**Children:** Recommended dosage for children with urinary tract infections or acute otitis media—8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours, in two divided doses for 10 days. Use identical daily dosage for 5 days for shigellosis. A guide follows:

Children two months of age or older:

Weight		Dose—every 12 hours	
lbs	kgs	Teaspoonfuls	Tablets
22	10	1 teasp. (5 ml)	½ tablet
44	20	2 teasp. (10 ml)	1 tablet
66	30	3 teasp. (15 ml)	1½ tablets
88	40	4 teasp. (20 ml)	2 tablets or 1 DS tablet

For patients with renal impairment:

Creatinine Clearance (ml/min)	Recommended Dosage Regimen
Above 30	Usual standard regimen
15-30	½ the usual regimen
Below 15	Use not recommended

**PNEUMOCYSTIS CARINII PNEUMONITIS:** Recommended dosage: 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours in equal doses every 6 hours for 14 days. See complete product information for suggested children's dosage table.

**Supplied:** *Double Strength (DS) tablets*, each containing 160 mg trimethoprim and 800 mg sulfamethoxazole, bottles of 100; *Tel-E-Dose®* packages of 100; *Prescription Paks* of 20. *Tablets*, each containing 80 mg trimethoprim and 400 mg sulfamethoxazole —bottles of 100 and 500; *Tel-E-Dose®* packages of 100; *Prescription Paks* of 40, available singly and in trays of 10. *Oral suspension*, containing in each teaspoonful (5 ml) the equivalent of 40 mg trimethoprim and 200 mg sulfamethoxazole, fruit-licorice flavored—bottles of 16 oz (1 pint).

## LETTERS TO THE EDITOR

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These points notwithstanding, Rockey et al are to be commended for making a significant contribution to our ability to treat patients in a rational and cost-effective manner.

Robert D. Gillette, MD

Associate Professor

Department of Family Medicine

Medical College of Ohio at Toledo

Director, Riverside Family

Practice Center

Toledo, Ohio

## Etiology of Ampicillin Rash

To the Editor:

I am writing in reference to the article "The Ampicillin Rash as a Diagnostic and Management Problem: Case Reports and Literature Review" (Geyman JP, Erikson S: *J Fam Pract* 7:493, 1978). This is an important article because of the high frequency of ampicillin rash encountered in private practice and because the conclusions the article reaches are far from common knowledge to the private practitioner. However, I feel that one point needs further clarification.

I agree that there is "strong evidence against any allergic basis for the maculopapular skin rash," but I feel that one must be a bit more cautious in the case of the individual who develops a maculopapular rash within 24 hours of ampicillin administration. Geyman and Erikson indirectly touch on this point when they describe the "typical nonallergic maculopapular ampicillin rash" as occurring "after four or more days of ampicillin therapy." The final chapter has not been written concerning this situation, and I think it medically prudent to view these patients as "allergic."

R. E. Townsend, MD

Marion, Virginia



Roche Laboratories  
 Division of Hoffmann-La Roche Inc.  
 Nutley, New Jersey 07110