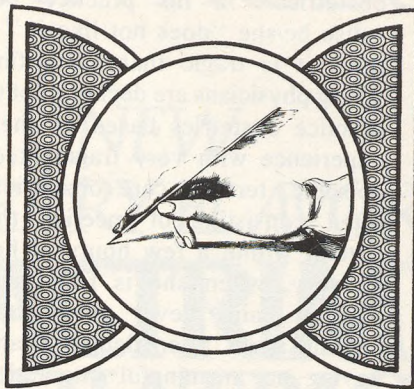


# Letters to the Editor



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.

## Legal Risks of Polio Immunization

To the Editor:

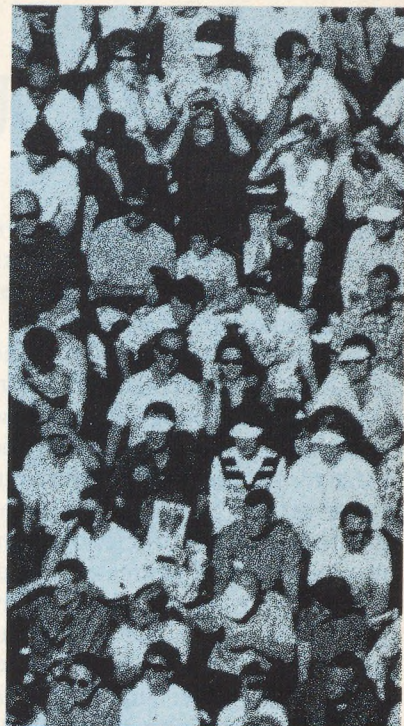
Dr. H.V. Wyatt's article in the September issue of *The Journal of Family Practice* (7:469, 1978), "Polio Immunization: Benefits and Risks," is an encouraging analysis of the value of polio immunization. It seems quite clear that a balance of the relative risks favors immunization.

I must, however, clarify one misconception in the legal analysis of the risks involved. Dr. Wyatt asserted that, "there has not been an action by a contact vaccine-associated case against a manufacturer or the US government." That assertion is not correct. One mother has successfully sued a manufacturer when she contracted polio with resulting paralysis after her child had been immunized. In *Givens vs Lederle*, 556 F.2d 1341 (1977), the manufacturer was found liable for failing to forewarn of the risk of this complication. Interestingly enough, the physician who had administered the immunization without warning the patient was exculpated in the litigation. Ordinarily, the action of a physician, as an intermediary, relieves the manufacturer of responsibility.

As a practical matter, the legal risks involved in undertaking an immunization program can be reduced by warning of the risk of paralysis to those being immunized (and their parents or legal guardians if children are to receive the vaccine). Much of the litigation involving polio vaccines has been based upon a failure to warn of the risks so that the patient or the parents can give an informed consent.

The other successful legal theory against polio vaccine manufacturers has been related to the company's methods of defense. The manufacturers have asserted that the patient suffered polio as a result of contact with a wild strain of virus and the claimants have asserted that the manufacturer gave the vaccinee a defective vaccine. If the manufacturers had acknowledged that there is an inherent risk of the vaccine causing paralysis, possibly because of the unavoidable reversion of the strain to a virulent form, then the manufacturer could have been relieved of liability, on the grounds that this was an unavoidable risk. The manufacturer's legal defense tac-

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tics in the past created their own liability exposure risks. These risks can be minimized by the proper dissemination of the information.

The other legal risk to the physician is punctuated by Dr. Wyatt's description of vaccine complications. A physician may be liable for failure to try to screen out those at risk. As Dr. Wyatt has pointed out in his article, those individuals who are at greatest risk of contracting polio already have immune deficiencies, and a physician may detect those in this risk category by his screening efforts. A reasonable screening effort, which good practice should require anyway, should be sufficient to avoid liability risks.

Some may interpret this as a sour note because of the liability risks associated with polio immunization. Such an impression is not intended. The practicing physician has little risk in a polio vaccination program so long as proper warnings are given, and a proper history and screening are undertaken.

Marden G. Dixon, MD, JD  
Author, *Drug Product Liability*  
Provo, Utah

### Obstetrics in Family Practice

To the Editor:

I read with great enthusiasm and interest the article by Dr. David A. Lynch, "Obstetrics in Family Practice: A Model for Residency Training" (*J Fam Pract* 7:723, 1978). In my position as a family practice educator I am very often confronted with the senior medical student residency candidate or the first year family practice resident who has, based on his experience on isolated block obstetrical rotations, "decided not to do

obstetrics" in his practice because he/she "does not like it." I think it is tragic that many fine young physicians are deciding not to practice obstetrics based on their experience with very fragmented, episodic, tertiary care obstetrics, often consisting of meeting the patient within a few hours of her delivery, when she is frightened and in pain, never seeing the patient again after delivery, and having no meaningful interaction with the patient or her family.

Dr. Lynch very graphically points out the fact that the real value of and rewards for practicing obstetrics lie in the mode of longitudinal continuity of care.

I compliment Dr. Lynch on his fine article. I will use it in the future to help me try to convince medical students and family practice residents to include obstetrics in their practice plans.

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Charleston

### Management of Chronic Pain

To the Editor:

I want first to commend Drs. Bergman and Werblun on their excellent article "Chronic Pain: A Review for the Family Physician" (*J Fam Pract* 7:685, 1978). The time contingency plan which they advocate in the management of pain is a marked improvement over pain-contingent therapy. I believe that this approach is further enhanced when the physician deliberately avoids the use of the term "pain" in his treatment of patients with pain. The patient with chronic pain is particularly receptive to the physician's verbal and

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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 methyldopa, 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).



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# BACTRIM™



(trimethoprim and sulfamethoxazole)

LETTERS TO THE EDITOR

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

**Indications and Usage:** For the treatment of urinary tract infections due to susceptible strains of the following organisms: *Escherichia coli*, *Klebsiella-Enterobacter*, *Proteus mirabilis*, *Proteus vulgaris*, *Proteus morganii*. It is recommended that initial episodes of uncomplicated urinary tract infections be treated with a single effective antibacterial agent rather than the combination. *Note:* The increasing frequency of resistant organisms limits the usefulness of all antibacterials, especially in these urinary tract infections.

**For acute otitis media in children due to susceptible strains of *Haemophilus influenzae* or *Streptococcus pneumoniae* when in physician's judgment it offers an advantage over other antimicrobials.** Limited clinical information presently available on effectiveness of treatment of otitis media with Bactrim when infection is due to ampicillin-resistant *Haemophilus influenzae*. To date, there are limited data on the safety of repeated use of Bactrim in children under two years of age. Bactrim is not indicated for prophylactic or prolonged administration in otitis media at any age.

**For enteritis due to susceptible strains of *Shigella flexneri* and *Shigella sonnei* when antibacterial therapy is indicated.**

**Also for the treatment of documented *Pneumocystis carinii* pneumonitis.** To date, this drug has been tested only in patients 9 months to 16 years of age who were immunosuppressed by cancer therapy.

**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 tonsilopharyngitis 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, periarthritis 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, 10, 5, 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. **Pediatric Suspension,** containing in each teaspoonful (5 ml) the equivalent of 40 mg trimethoprim and 200 mg sulfamethoxazole, cherry flavored—bottles of 16 oz (1 pint). **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).

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nonverbal communications. If, in using the time contingency plan, we advise patients to take their specific medication periodically "for pain" or "for relief of pain," one of the messages the patient receives is that "my doctor expects me to continue to have some pain." However, if we advise a patient to take the medication periodically "for comfort," one of the messages the patient receives is, "my doctor expects that I can have comfort." There is more hope in the latter message and, as the authors clearly state, there is more to pain management than reliance on drug therapy.

Some of the therapeutic modalities discussed included relaxation therapy, biofeedback, and operant programs. For the sake of completion I want to add a very powerful modality in the management of pain and that is hypnosis. Pain patients are usually motivated to obtain relief and this is especially applicable to cancer patients. Under the guidance of skilled therapists these patients can learn to handle their discomfort better. The progressive relaxation without undesirable side effects, which patients can learn to achieve with the aid of hypnosis, is unequalled by any other form of therapy. *The American Journal of Clinical Hypnosis and the International Journal of Clinical and Experimental Hypnosis* abound with articles which discuss the utility of hypnosis in the management of pain. The Societies which publish these journals also offer training programs at basic, intermediate, and advanced levels which will help qualify family physicians in the use of medical hypnosis.

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