'Loopholes' weaken hospital accreditation policy

To the Editor:

I read your editorial "Hospital accreditation pounds another 'nail' in the 'smoking' coffin (*JAOA* 1991;91:1171) with pleasure. However, this pleasure soon turned to dismay as I realized that the tough new accreditation policy of the American Osteopathic Association is full of holes for the convenience of nearly anyone who may not want to contribute to the establishment of a smokeless society.

Specifically, the policy states that hospitals may make exceptions to their policy where "abrupt cessation of smoking would be detrimental to the patient." I tried to think of those medical conditions that would be exacerbated by abrupt cessation of cigarette smoking and thereby cause harm to the patient. My list was *very* short.

Another provision in this policy states that hospitals "will segregate, where practical, patients authorized to smoke from nonsmoking patients." When is it *not* practical to segregate smokers from nonsmokers in any environment, especially that of a hospital? Even the US military, traditionally a hard-drinking, heavy-smoking group, now has established totally smoke-free hospitals. Anyone in a military hospital must now step outside in designated areas to smoke. Why can't the rest of the hospitals make this logical transition? In my opinion, the potential for a malpractice suit lies behind this failure to segregate.

In short, what began and ended as a triumphant proclamation, seemed, in the middle, to be little more than loopholed lip service. I hope that those persons in politically powerful positions can, in the future, adopt a policy more consistent with those of us dedicated to saving and improving lives.

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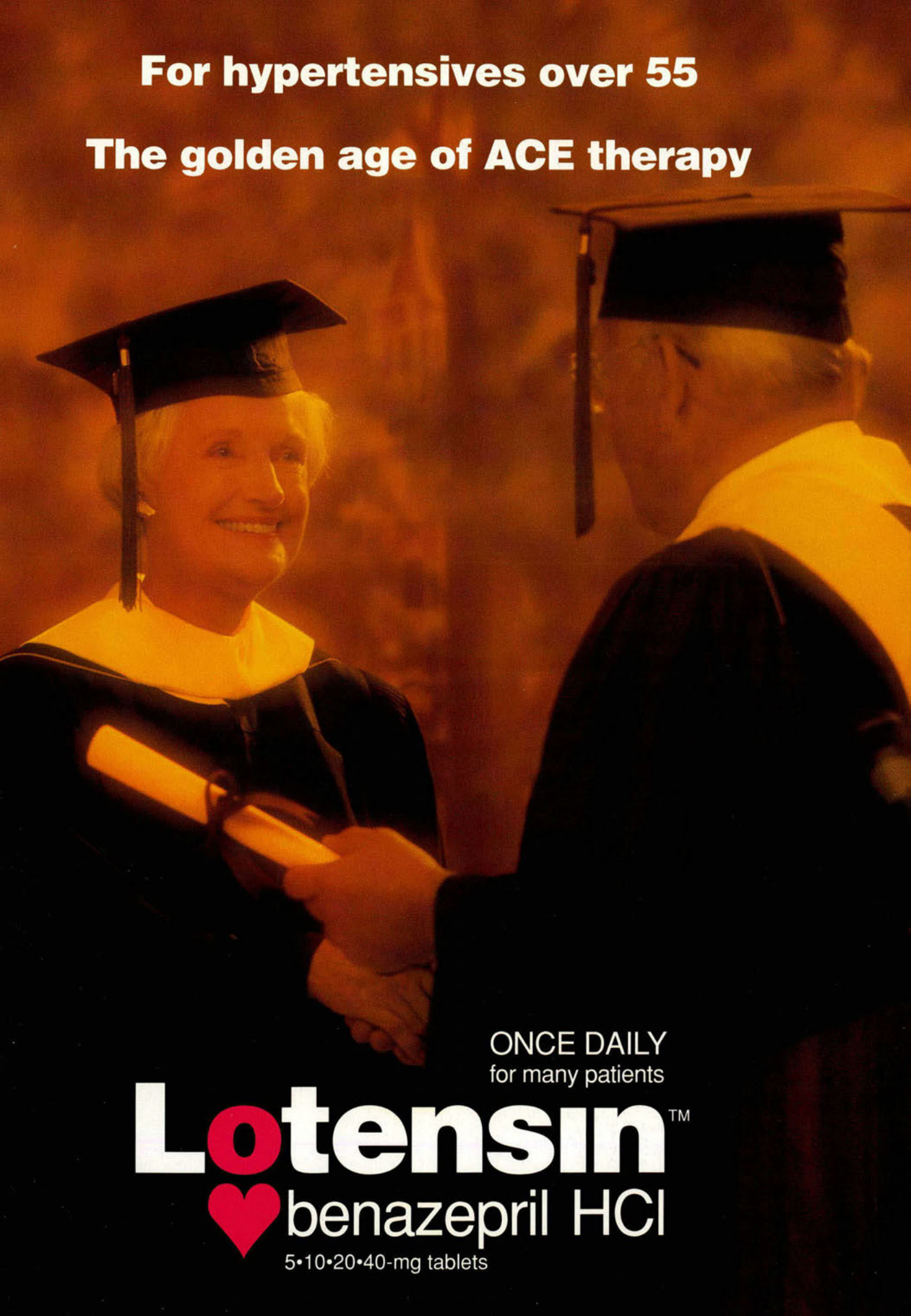
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Safe and well-tolerated regardless of age.[2] In controlled clinical trials, overall incidence of adverse events comparable to placebo. Incidence of cough statistically significant.[3]

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- digoxin[3]
- propranolol[3]
- furosemide[6]
- warfarin[5]
- cimetidine[3]
- chlorthalidone[3]
- naproxen[3]
- atenolol[3]
- hydrochlorothiazide[7]

The evaluation of any hypertensive patient should include renal function studies. ACE inhibition may cause changes in renal function in susceptible individuals. Lotensin is contraindicated in patients who are hypersensitive to this product or to any other ACE inhibitor. Angioedema has been reported in patients receiving ACE inhibitors. Please consult brief summary of Prescribing Information, including the "Drug Interactions and Precautions - Impaired Renal Function" sections on last page.

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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE INSERT)

INDICATIONS AND USAGE Lotensin is indicated for the treatment of hypertension. It may be used alone or in combination with thiazide diuretics.

In using Lotensin, consideration should be given to the fact that another angiotensin-converting enzyme inhibitor, captopril, has caused agranulocytosis, particularly in patients with renal impairment or collagen-vascular disease. Available data are insufficient to show that Lotensin does not have a similar risk (see WARNINGS).

CONTRAINDICATIONS Lotensin is contraindicated in patients who are hypersensitive to this product or to any other ACE inhibitor.

WARNINGS-Angioedema Angioedema of the face, extremities, lips, tongue, glottis, and larynx has been reported in patients treated with angiotensin-converting enzyme inhibitors. In U.S. clinical trials, symptoms consistent with angioedema were seen in none of the subjects who received placebo and in about 0.5% of the subjects who received Lotensin. Angioedema associated with laryngeal edema can be fatal. If laryngeal stridor or angioedema of the face, tongue, or glottis occurs, treatment with Lotensin should be discontinued and appropriate therapy instituted immediately. **Where there is involvement of the tongue, glottis, or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine injection 1:1000 (0.3 mL to 0.5 mL) should be promptly administered (see ADVERSE REACTIONS).**

Hypotension Lotensin can cause symptomatic hypotension. Like other ACE inhibitors, benazepril has been only rarely associated with hypotension in uncomplicated hypertensive patients. Symptomatic hypotension is most likely to occur in patients who have been volume- and/or salt-depleted as a result of prolonged diuretic therapy, dietary salt restriction, dialysis, diarrhea, or vomiting. Volume- and/or salt-depletion should be corrected before initiating therapy with Lotensin.

In patients with congestive heart failure, with or without associated renal insufficiency, ACE inhibitor therapy may cause excessive hypotension, which may be associated with oliguria or azotemia and, rarely, with acute renal failure and death. In such patients, Lotensin therapy should be started under close medical supervision; they should be followed closely for the first 2 weeks of treatment and whenever the dose of benazepril or diuretic is increased.

If hypotension occurs, the patient should be placed in a supine position, and, if necessary, treated with intravenous infusion of physiological saline. Lotensin treatment usually can be continued following restoration of blood pressure and volume.

Neutropenia/Agranulocytosis Another angiotensin-converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients, but more frequently in patients with renal impairment, especially if they also have a collagen-vascular disease such as systemic lupus erythematosus or scleroderma. Available data from clinical trials of benazepril are insufficient to show that benazepril does not cause agranulocytosis at similar rates. Monitoring of white blood cell counts should be considered in patients with collagen-vascular disease, especially if the disease is associated with impaired renal function.

Fetal/Neonatal Morbidity and Mortality ACE inhibitors can cause fetal and neonatal morbidity and mortality when administered to pregnant women.

When ACE inhibitors have been used during the second and third trimesters of pregnancy, there have been reports of neonatal hypotension, renal failure, skull hypoplasia, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios has been associated with fetal limb contractures, craniofacial malformations, hypoplastic lung development, and intrauterine growth retardation. Prematurity and patent ductus arteriosus have been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure or to the mother's underlying disease.

It is not known whether exposure limited to the first trimester can adversely affect fetal outcome.

A patient who becomes pregnant while taking ACE inhibitors, or who takes ACE inhibitors when already pregnant, should be apprised of the potential hazard to her fetus. If she continues to receive ACE inhibitors during the second or third trimester of pregnancy, frequent ultrasound examinations should be performed to look for oligohydramnios. When oligohydramnios is found, ACE inhibitors should generally be discontinued.

Infants with histories of in utero exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hypokalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Benazepril could theoretically be removed from the neonatal circulation by exchange transfusion, but no experience with this procedure has been reported.

At doses that did not induce maternal toxicity, no embryotoxic, fetotoxic or teratogenic effects of Lotensin were seen in studies of pregnant rats, mice, and rabbits. On a mg/m^2 basis, the doses used in these studies were 60 times (in rats), 9 times (in mice), and more than 0.8 times (in rabbits) the maximum recommended human dose (assuming a 50 kg woman). On a mg/kg basis these multiples are 300 times (in rats), 90 times (in mice) and more than 3 times (in rabbits) the maximum recommended human dose.

PRECAUTIONS-General ***Impaired Renal Function:*** As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin-converting enzyme inhibitors, including Lotensin, may be associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. In a small study of hypertensive patients with renal artery stenosis in a solitary kidney or bilateral renal artery stenosis, treatment with Lotensin was associated with increases in blood urea nitrogen and serum creatinine; these increases were reversible upon discontinuation of Lotensin or diuretic therapy, or both. When such patients are treated with ACE inhibitors, renal function should be monitored during the first few weeks of therapy. Some hypertensive patients with no apparent preexisting renal vascular disease have developed increases in blood urea nitrogen and serum creatinine, usually minor and transient, especially when Lotensin has been given concomitantly with a diuretic. This is more likely to occur in patients with preexisting renal impairment. Dosage reduction of Lotensin and/or discontinuation of the diuretic may be required. **Evaluation of the hypertensive patient should always include assessment of renal function (see DOSAGE AND ADMINISTRATION).** ***Hyperkalemia:*** In clinical trials, hyperkalemia (serum potassium at least 0.5 mEq/L greater than the upper limit of normal) occurred in approximately 1% of hypertensive patients receiving Lotensin. In most cases, these were isolated values which resolved despite continued therapy. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements, and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with Lotensin (see Drug Interactions). ***Impaired Liver Function:*** In patients with hepatic dysfunction due to cirrhosis, levels of benazeprilat are essentially unaltered. ***Surgery/Anesthesia:*** In patients undergoing surgery or during anesthesia with agents that produce hypotension, benazepril will block the angiotensin II formation that could otherwise occur secondary to compensatory renin release. Hypotension that occurs as a result of this mechanism can be corrected by volume expansion.

Information for Patients - ***Angioedema:*** Angioedema, including laryngeal edema, can occur with treatment with ACE inhibitors, especially following the first dose. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, eyes, lips, or tongue, or difficulty in breathing) and to take no more drug until they have consulted with the prescribing physician. ***Symptomatic Hypotension:*** Patients should be cautioned that lightheadedness can occur, especially during the first days of therapy, and it should be reported to the prescribing physician. Patients should be told that if syncope occurs, Lotensin should be discontinued until the prescribing physician has been consulted.

All patients should be cautioned that inadequate fluid intake or excessive perspiration, diarrhea, or vomiting can lead to an excessive fall in blood pressure, with the same consequences of lightheadedness and possible syncope. ***Hyperkalemia:*** Patients should be told not to use potassium supplements or salt substitutes containing potassium without consulting the prescribing physician. ***Neutropenia:*** Patients should be told to promptly report any indication of infection (e.g., sore throat, fever), which could be a sign of neutropenia.

Drug Interactions - ***Diuretics:*** Patients on diuretics, especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with Lotensin. The possibility of hypotensive effects with Lotensin can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with Lotensin. If this is not possible, the starting dose should be reduced (see DOSAGE AND ADMINISTRATION). ***Potassium Supplements and Potassium-Sparing Diuretics:*** Lotensin can attenuate potassium loss caused by thiazide diuretics. Potassium-sparing diuretics (spironolactone, amiloride, triamterene, and others) or potassium supplements can increase the risk of hyperkalemia. Therefore, if concomitant use of such agents is indicated, they should be given with caution, and the patient's serum potassium should be monitored frequently. ***Oral Anticoagulants:*** Interaction studies with warfarin and acenocoumarol failed to identify any clinically important effects on the serum concentrations or clinical effects of these anticoagulants. ***Lithium:*** Increased serum lithium levels and symptoms of lithium toxicity have been reported in patients receiving ACE inhibitors during therapy with lithium. These drugs should be coadministered with caution, and frequent monitoring of serum lithium levels is recommended. If a diuretic is also used, the risk of lithium toxicity may be increased. ***Other:*** No clinically important pharmacokinetic interactions occurred when Lotensin was administered concomitantly with hydrochlorothiazide, chlorthalidone, furosemide, digoxin, propranolol, atenolol, naproxen, or cimetidine.

Lotensin has been used concomitantly with beta-adrenergic-blocking agents, calcium-channel-blocking agents, diuretics, digoxin, and hydralazine, without evidence of clinically important adverse interactions. Benazepril, like other ACE inhibitors, has had less than additive effects with beta-adrenergic blockers, presumably because both drugs lower blood pressure by inhibiting parts of the renin-angiotensin system.

Carcinogenesis, Mutagenesis, Impairment of Fertility No evidence of carcinogenicity was found when benazepril was administered by gavage to rats and mice for up to two years at doses of up to 150 mg/kg/day. When compared on the basis of body weights, this dose is 110 times the maximum recommended human dose. When compared on the basis of body surface areas, this dose is 18 and 9 times (rats and mice, respectively) the maximum recommended human dose (calculations assume a patient weight of 60 kg). No mutagenic activity was detected in the Ames test in bacteria (with or without metabolic activation), in an in vitro test for forward mutations in cultured mammalian cells, or in a nucleus anomaly test. In doses of 50-500 mg/kg/day (6-60 times the maximum recommended human dose based on mg/m^2 comparison and 37-375 times the maximum recommended human dose based on a mg/kg comparison), Lotensin had no adverse effect on the reproductive performance of male and female rats.

Pregnancy Category D See WARNINGS, Fetal/Neonatal Morbidity and Mortality.

Nursing Mothers Minimal amounts of unchanged benazepril and of benazeprilat are excreted into the breast milk of lactating women treated with benazepril. A newborn child ingesting entirely breast milk would receive less than 0.1% of the mg/kg maternal dose of benazepril and benazeprilat.

Geriatric Use Of the total number of patients who received benazepril in U.S. clinical studies of Lotensin, 18% were 65 or older while 2% were 75 or older. No overall differences in effectiveness or safety were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Pediatric Use Safety and effectiveness in children have not been established.

ADVERSE REACTIONS Lotensin has been evaluated for safety in over 6000 patients with hypertension; over 700 of these patients were treated for at least one year. The overall incidence of reported adverse events was comparable in Lotensin and placebo patients.

The reported side effects were generally mild and transient, and there was no relation between side effects and age, duration of therapy, or total dosage within the range of 2 to 80 mg. Discontinuation of therapy because of a side effect was required in approximately 5% of U.S. patients treated with Lotensin and in 3% of patients treated with placebo.

The most common reasons for discontinuation were headache (0.6%) and cough (0.5%).

In placebo-controlled trials, cough was reported by 68 of 2004 benazepril-treated patients (3.4%) and by 7 of 525 placebo-treated patients (1.3%). This was the only adverse effect with incidence at least 1% that was significantly more frequent in benazepril-treated patients than in patients treated with placebo.

The side effects considered possibly or probably related to study drug that occurred in U.S. controlled trials in more than 1% of patients treated with Lotensin are shown below.

PATIENTS IN U.S. PLACEBO-CONTROLLED STUDIES

	LOTENSIN (N = 1629)		PLACEBO (N = 498)	
	N	%	N	%
Headache	82	5.0	21	4.2
Dizziness	53	3.3	12	2.4
Fatigue	42	2.6	11	2.2
Cough	31	1.9	5	1.0
Nausea	23	1.4	5	1.0

Other adverse experiences reported in controlled clinical trials (in less than 1% of benazepril patients), and rarer events seen in postmarketing experience, include the following (in some, a causal relationship to drug use is uncertain): ***Cardiovascular:*** Symptomatic hypotension was seen in 0.3% of patients, postural hypotension in 0.4%, and syncope in 0.1%; these reactions led to discontinuation of therapy in 4 patients who had received benazepril monotherapy and in 9 patients who had received benazepril with hydrochlorothiazide (see PRECAUTIONS and WARNINGS). Other reports included angina pectoris, palpitations, and peripheral edema. ***Renal:*** Of hypertensive patients with no apparent preexisting renal disease, about 2% have sustained increases in serum creatinine to at least 150% of their baseline values while receiving Lotensin, but most of these increases have disappeared despite continuing treatment. A much smaller fraction of these patients (less than 0.1%) developed simultaneous (usually transient) increases in blood urea nitrogen and serum creatinine. ***Angioedema:*** Angioedema has been reported in patients receiving ACE inhibitors. During clinical trials in hypertensive patients with benazepril, 0.5% of patients experienced edema of the lips or face without other manifestations of angioedema. Angioedema associated with laryngeal edema and/or shock may be fatal. If angioedema of the face, extremities, lips, tongue, or glottis and/or larynx occurs, treatment with Lotensin should be discontinued and appropriate therapy instituted immediately (see WARNINGS). ***Gastrointestinal:*** Constipation, gastritis, vomiting, and melena. ***Dermatologic:*** Apparent hypersensitivity reactions (manifested by dermatitis, pruritis, or rash) and flushing. ***Neurologic and Psychiatric:*** Anxiety, decreased libido, hypertonia, insomnia, nervousness, and paresthesia. ***Other:*** Arthralgia, arthritis, asthenia, asthma, bronchitis, dyspnea, impotence, infection, myalgia, sinusitis, sweating, and urinary tract infection.

Clinical Laboratory Test Findings

Creatinine and Blood Urea Nitrogen: Of hypertensive patients with no apparent preexisting renal disease, about 2% have sustained increases in serum creatinine to at least 150% of their baseline values while receiving Lotensin, but most of these increases have disappeared despite continuing treatment. A much smaller fraction of these patients (less than 0.1%) developed simultaneous (usually transient) increases in blood urea nitrogen and serum creatinine. None of these increases required discontinuation of treatment. Increases in these laboratory values are more likely to occur in patients with renal insufficiency or those pretreated with a diuretic and, based on experience with other ACE inhibitors, would be expected to be especially likely in patients with renal artery stenosis (see PRECAUTIONS, General).

Potassium: Since benazepril decreases aldosterone secretion, elevation of serum potassium can occur. Potassium supplements and potassium-sparing diuretics should be given with caution, and the patient's serum potassium should be monitored frequently (see PRECAUTIONS). ***Hemoglobin:*** Decreases in hemoglobin (a low value and a decrease of 5 g/dL) were rare, occurring in only 1 of 2014 patients receiving Lotensin alone and in 1 of 1357 patients receiving Lotensin plus a diuretic. No U.S. patients discontinued treatment because of decreases in hemoglobin. ***Other (causal relationships***

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unknown): Clinically important changes in standard laboratory tests were rarely associated with Lotensin administration. Elevations of liver enzymes, serum bilirubin, uric acid, and blood glucose have been reported, as have scattered incidents of hyponatremia, electrocardiographic changes, leukopenia, eosinophilia, and proteinuria. In U.S. trials, less than 0.5% of patients discontinued treatment because of laboratory abnormalities.

OVERDOSAGE Single oral doses of 3 g/kg benazepril were associated with significant lethality in mice. Rats however, tolerated single oral doses of up to 6 g/kg. Reduced activity was seen at 1 g/kg in mice and at 5 g/kg in rats. Human overdoses of benazepril have not been reported, but the most common manifestation of human benazepril overdosage is likely to be hypotension.

Laboratory determinations of serum levels of benazepril and its metabolites are not widely available, and such determinations have, in any event, no established role in the management of benazepril overdose.

No data are available to suggest physiological maneuvers (e.g., maneuvers to change the pH of the urine) that might accelerate elimination of benazepril and its metabolites. Benazeprilat can be removed from the body by dialysis, but this intervention should rarely, if ever, be required.

Angiotensin II could presumably serve as a specific antagonist-antidote in the setting of benazepril overdose, but angiotensin II is essentially unavailable outside of scattered research facilities. Because the hypotensive effect of benazepril is achieved through vasodilation and effective hypovolemia, it is reasonable to treat benazepril overdose by infusion of normal saline solution.

DOSAGE AND ADMINISTRATION The recommended initial dose for patients not receiving a diuretic is 10 mg once-a-day. The usual maintenance dosage range is 20-40 mg per day administered as a single dose or in two equally divided doses. A dose of 80 mg gives an increased response, but experience with this dose is limited. The divided regimen was more effective in controlling trough (pre-dosing) blood pressure than the same dose given as a once-daily regimen. Dosage adjustment should be based on measurement of peak (2-6 hours after dosing) and trough responses. If a once-daily regimen does not give adequate trough response an increase in dosage or divided administration should be considered. If blood pressure is not controlled with Lotensin alone, a diuretic can be added.

Total daily doses above 80 mg have not been evaluated.

Concomitant administration of Lotensin with potassium supplements, potassium salt substitutes, or potassium-sparing diuretics can lead to increases of serum potassium (see PRECAUTIONS).

In patients who are currently being treated with a diuretic, symptomatic hypotension occasionally can occur following the initial dose of Lotensin. To reduce the likelihood of hypotension, the diuretic should, if possible, be discontinued two to three days prior to beginning therapy with Lotensin (see WARNINGS). Then, if blood pressure is not controlled with Lotensin alone, diuretic therapy should be resumed.

If the diuretic cannot be discontinued, an initial dose of 5 mg Lotensin should be used to avoid excessive hypotension.

Dosage Adjustment in Renal Impairment

For patients with a creatinine clearance <30 mL/min/1.73 m^2 (serum creatinine >3 mg/dL), the recommended initial dose is 5 mg Lotensin once daily. Dosage may be titrated upward until blood pressure is controlled or to a maximum total daily dose of 40 mg.

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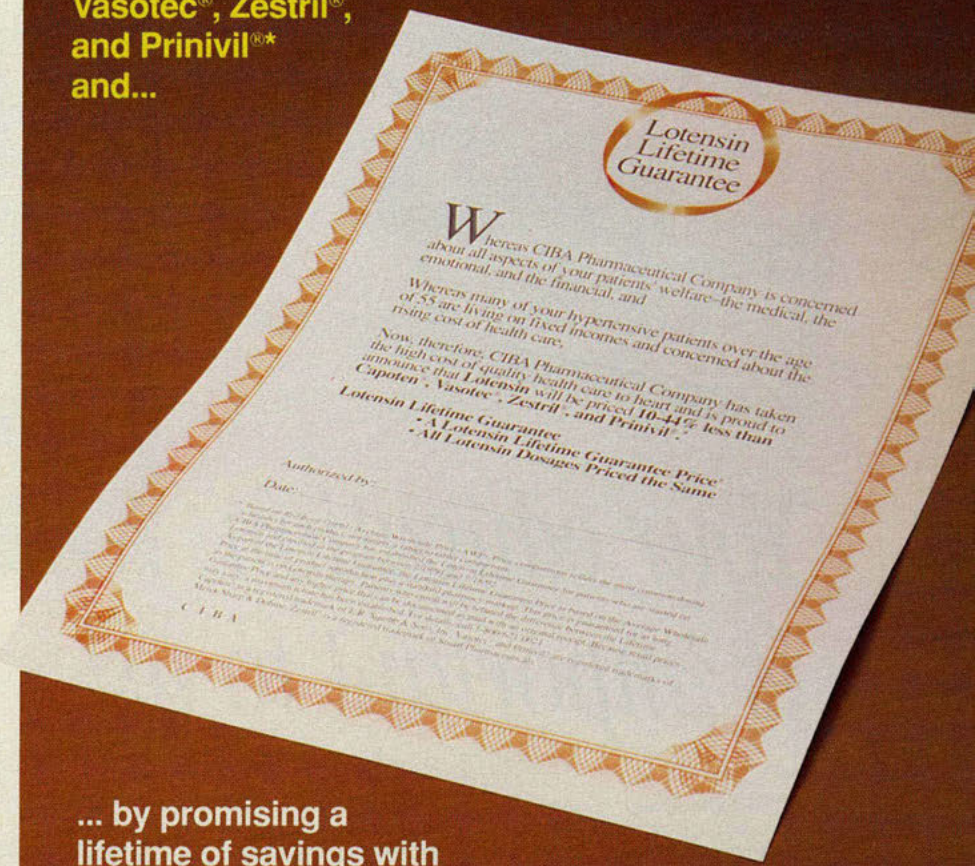

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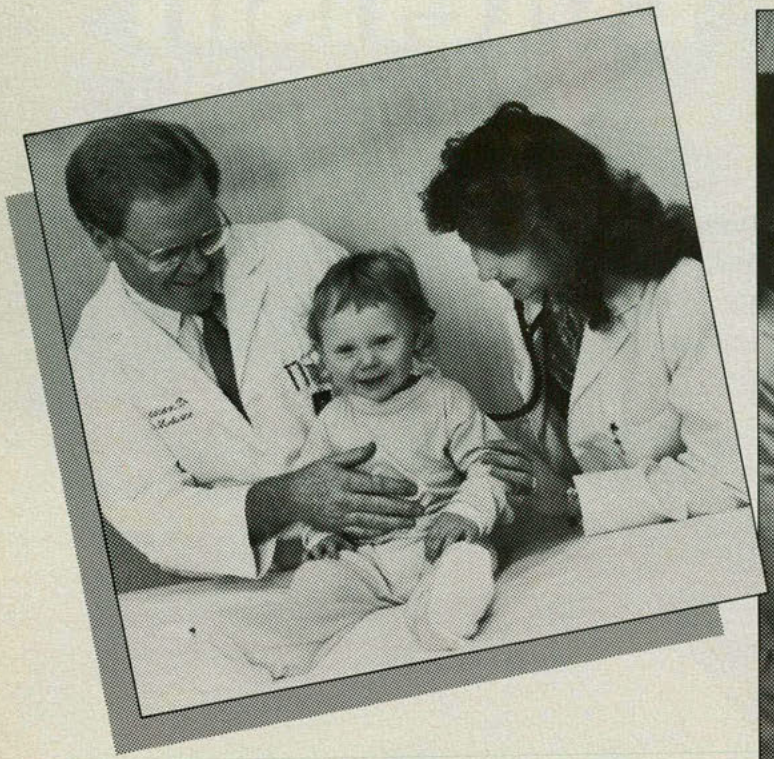

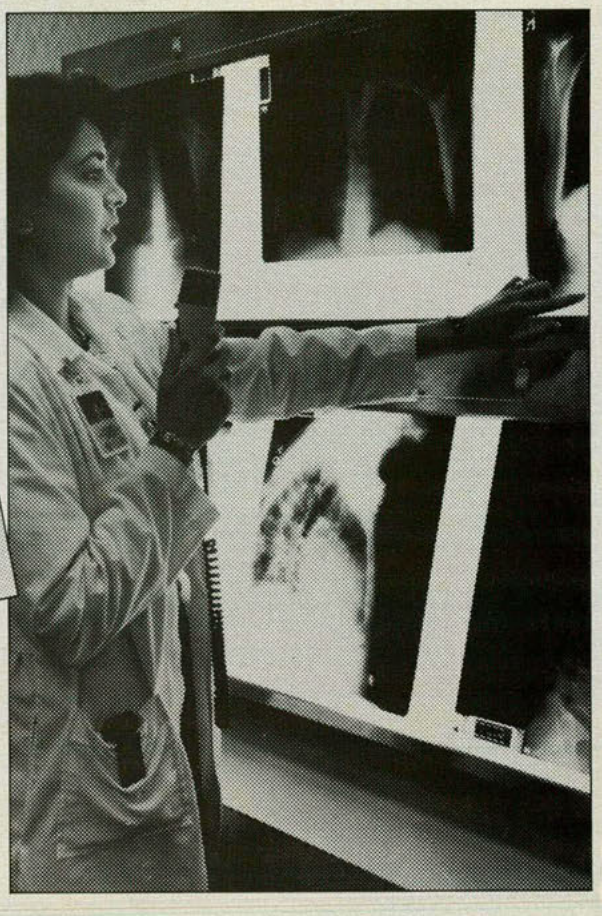

Your education is important to us!

Left Photo: Don Middleton, D.O., Resident, Tracy Middleton, D.O., Resident and "small" patient at FOH.

Right Photo: Sucheta Kulkarni, D.O., Intern

"Flint Osteopathic Hospital has provided acute and general health care for the Flint community for 50 years. The hospital is affiliated with Michigan State University and offers a full range of medical, surgical, emergency, and intensive care services. All medical and surgical subspecialties are covered. At FOH the intern and resident receives training in both outpatient ambulatory care as well as inpatient practices.

FOH, with 359 beds, is the largest osteopathic hospital in Michigan offering intern and residency training programs for osteopathic physicians. The medical education program is designed to provide a structured curriculum and experience in diagnosis and treatment. Morning reports and guest physician lectures occur daily. Reading lists and objectives have been developed for each service. A monthly journal club is conducted by each clinical department. EKG conferences are scheduled twice monthly. The FOH Congdon Lecture Series brings both D.O. and M.D. physicians to the hospital each month. Prominent practitioners, representative of both medical communities, share expertise in research findings during these monthly, day-long seminar presentations.

Ambulatory clinics have been established and provide longitudinal continuity training for interns and residents. Both traditional and alternative track internships are available at FOH. The hospital is a charter member of the Consortium of Osteopathic Graduate Medical Education and Training (COGMET) in association with Michigan State University."

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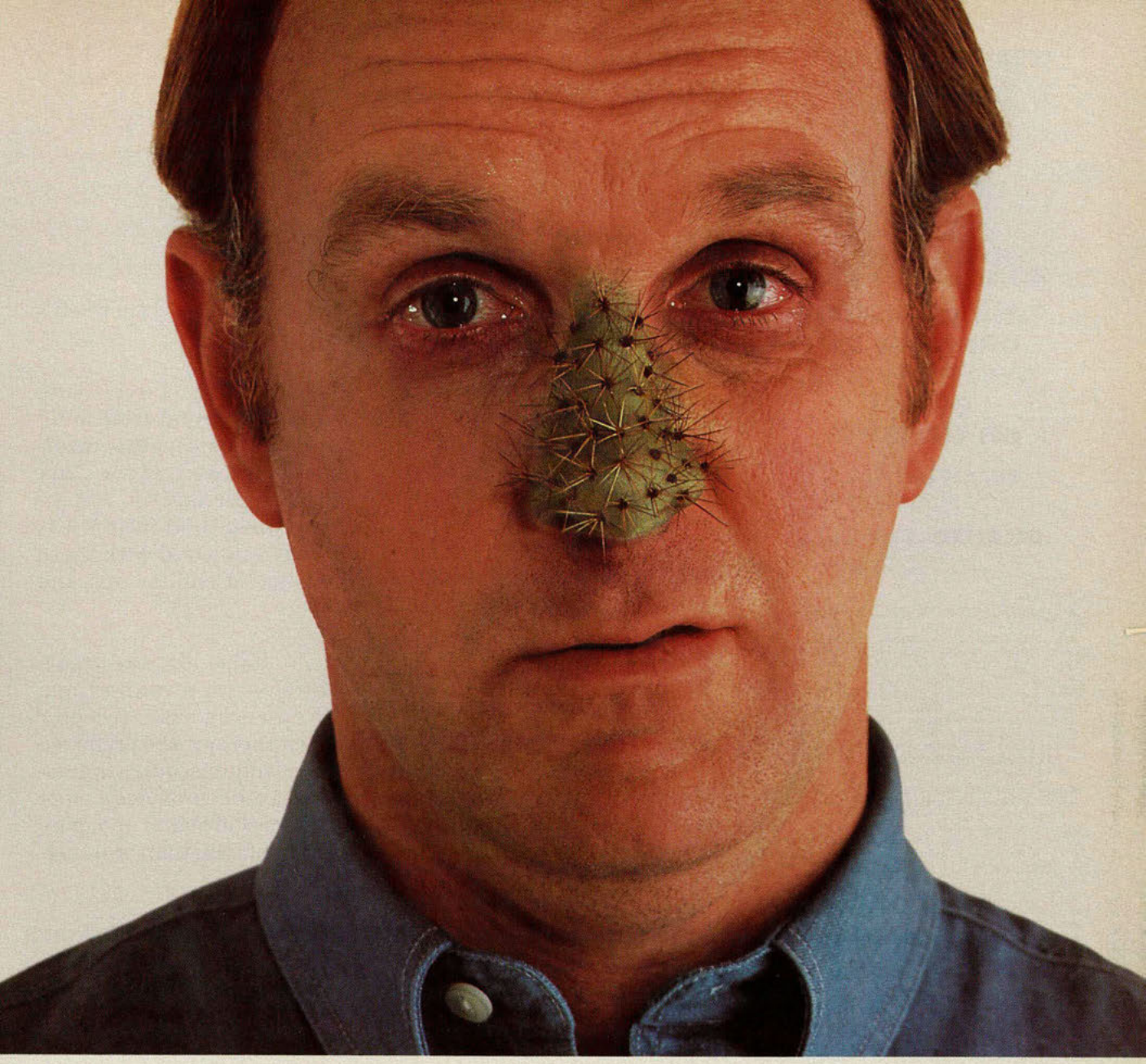

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