THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

VOLUME 17 NUMBER 7

Diabetes Care

JULY 1994

Original Articles

Short Reports

Case Reports

Technical Review

Commentaries

Editorial

Perspectives on the News

Tribute

American Diabetes Association

ISSN 0149-5992

He doesn't like to clean.	**No cleaning.**
He doesn't like to calibrate.	**No trouble to calibrate.**
He doesn't like to wipe.	**No wiping.**
He doesn't like to aim.	**No problem targeting test strip.**
He doesn't like to time.	**No timing.**
He doesn't like to squint.	**No hard-to-read display.**
He doesn't like to wait.	**No more than 40 seconds for results.**

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THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

VOLUME 17 NUMBER 7

Diabetes Care

Diabetes Care is a journal for the health-care practitioner that is intended to increase knowledge, stimulate research, and promote better management of people with diabetes mellitus. To achieve these goals, the journal publishes original articles on human studies in the areas of epidemiology, clinical trials, behavioral medicine, nutrition, education, health-care delivery, medical economics, and clinical care. The journal also publishes clinically relevant review articles, clinical observations, letters to the editor, and public health/medical news or points of view. Topics covered are of interest to clinically oriented physicians, researchers, epidemiologists, psychologists, diabetes educators, and other professionals.

All manuscripts and other editorial correspondence should be sent by first class mail to Allan L. Drash, MD, Editor, *Diabetes Care*, Children's Hospital, Rangos Research Center, 3705 Fifth Avenue, Pittsburgh, PA 15213; (412) 692-5851. Manuscripts and correspondence regarding review articles should be sent to Ralph A. DeFronzo, MD, Editor, *Diabetes Reviews*, Department of Medicine, Division of Diabetes, UT-HSCSA, 7703 Floyd Curl Drive, San Antonio, TX 78284.

Diabetes Care publishes only original material. When submitting a manuscript, authors must state in their transmittal letter that the material has not been previously published or is not currently being submitted to another journal.

Manuscripts should be prepared in accord with the requirements specified in the document "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," *New England Journal of Medicine* 324:424–428, 1991. "Instructions for Authors" containing specifications for manuscript preparation appears in the January and July issues.

Diabetes Care (ISSN 0149-5992) is published monthly by the American Diabetes Association, Inc., 1660 Duke Street, Alexandria, VA 22314. Individual subscription rates are $75 in the U.S., Canada, and Mexico (for Canada add 7% GST) and $130 for all other countries. Professional membership includes $50 designated for *Diabetes Care*. Single issues are $11 in the U.S., Canada, and Mexico (Canada add 7% GST) and $26.00 in all other countries. Second class postage paid at Alexandria, VA 22314, and at additional mailing offices. POSTMASTER: Send change of address to *Diabetes Care*, American Diabetes Association, Inc., Journal Subscriptions, Dept. 0028, Washington, DC 20073-0028.

Diabetes Care is listed in Science Citation Index, Current Contents/Life Sciences, Current Contents/Clinical Medicine, SCISEARCH, ISI/BIOMED databases, and Automatic Subject Citation Alert. *Diabetes Care* is available online on BRS Colleague. For more information call 800-955-0906. It is also available in machine-readable format from University Microfilms International. *Diabetes Care* is printed on acid-free paper starting with Vol. 11(1), 1988.

The mission of the American Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

American Diabetes Association.
ISSN 0149-5992
PRINTED IN THE USA.

Table of Contents (continued)

Letters

NOTICE TO AUTHORS

The American Diabetes Association will begin charging authors $50 per printed page beginning with articles published in the September 1994 issues of *Diabetes* and *Diabetes Care*. These charges will partially defray the rising costs of publication. Although editorial consideration and acceptance of a paper is in no way related to payment of a page charge, it is expected that authors will pay the page charge. In extraordinary cases, upon appeal by the author, the Publications Policy Committee may waive the page charge.

JULY AUTHOR INDEX (VOLUME 17, NUMBER 7)

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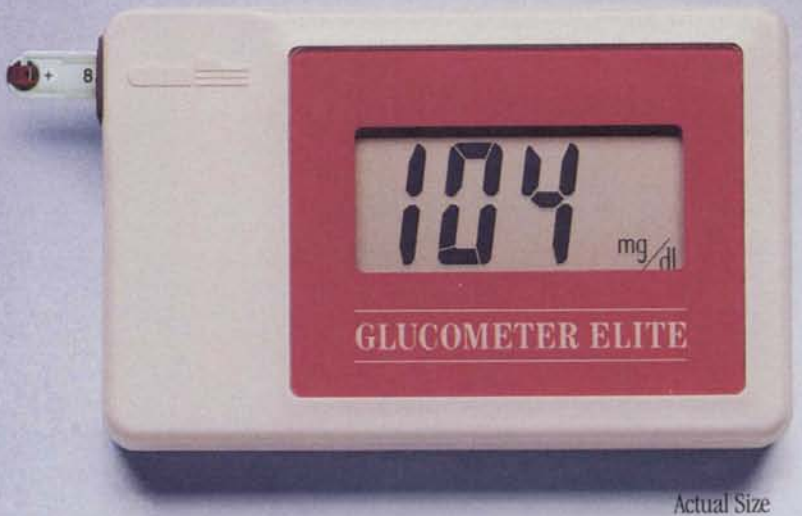

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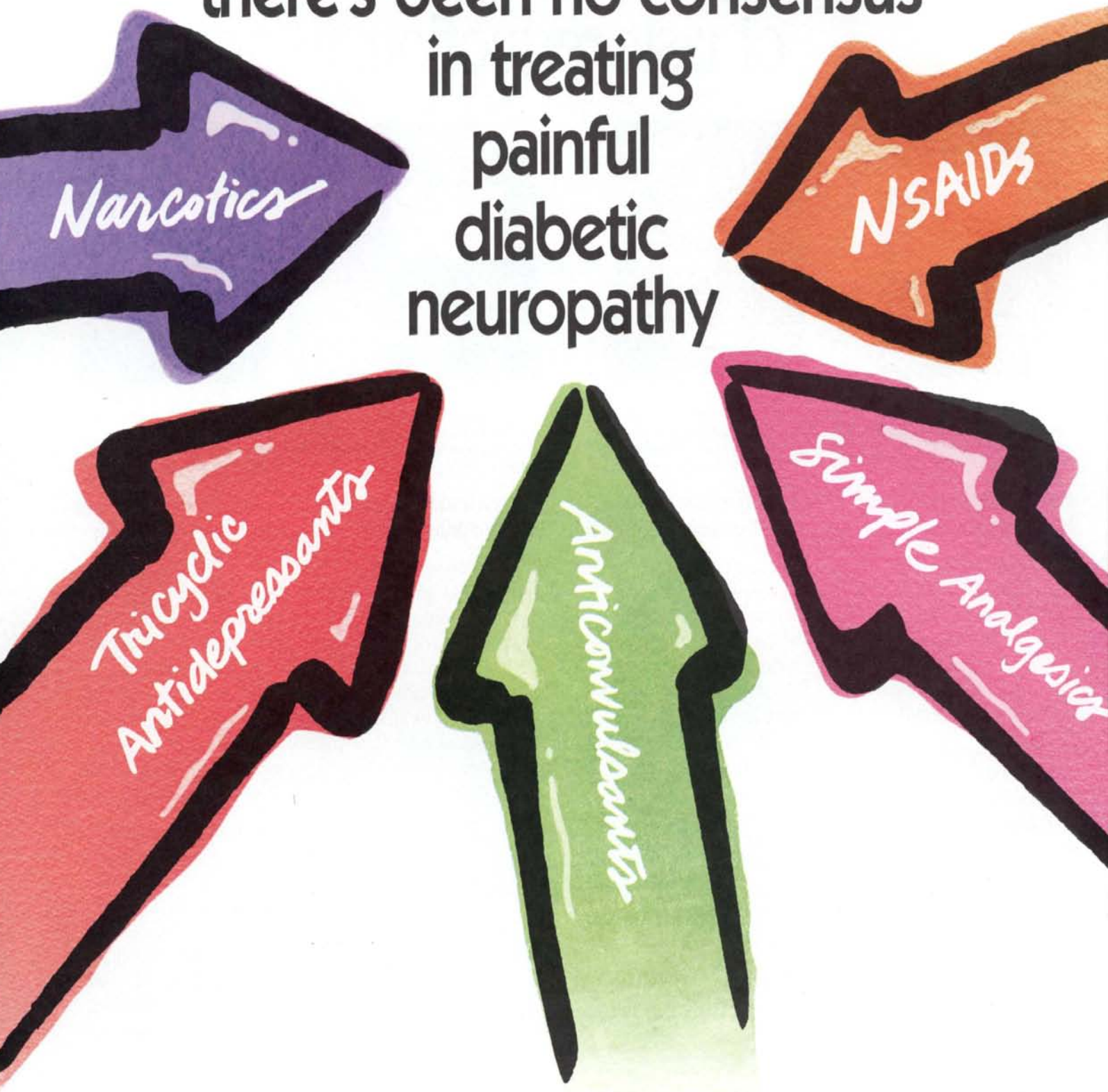
Until now, there's been no consensus in treating painful diabetic neuropathy



References:
1. Donofrio P, Walker F, Hunt V, et al. Treatment of painful diabetic neuropathy with topical capsaicin: a multicenter, double-blind, vehicle-controlled study. *Arch Intern Med.* 1991;151:2225-2229. **2.** Dailey GE III, Muchmore DP, Springer JW, et al. Effect of treatment with capsaicin on daily activities of patients with painful diabetic neuropathy. *Diabetes Care.* 1992;15:159-165. **3.** Tandan R, Lewis GA, Krusinski PB, Badger GB, Fries TJ. Topical capsaicin in painful diabetic neuropathy: controlled study with long-term follow-up. *Diabetes Care.* 1992;15:8-14. **4.** Scheffler NM, Sheitel PL, Lipton MN. Treatment of painful diabetic neuropathy with capsaicin 0.075%. *J Am Podiatr Med Assoc.* 1991;81(6):288-293.

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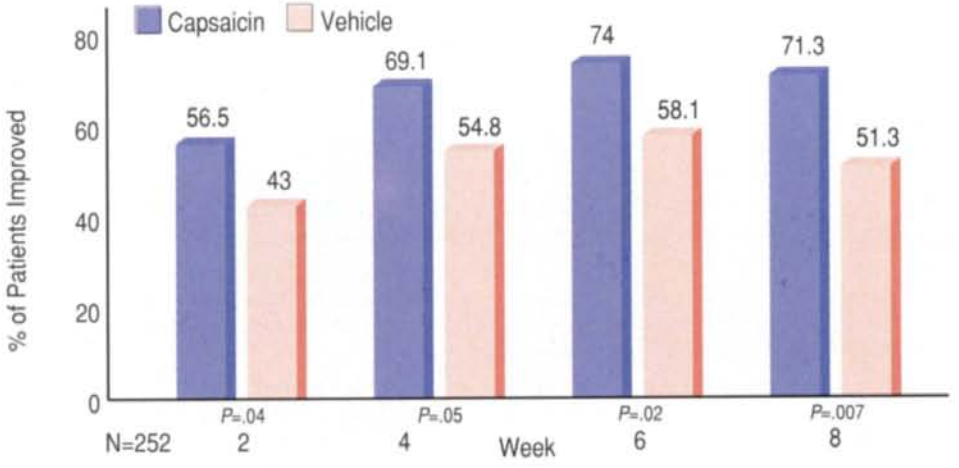

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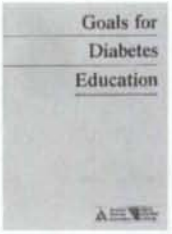
Goals for Diabetes Education



Education is key in managing diabetes and this book provides you with a logical, thorough approach to the initial and in-depth phases of educating patients. Covers specific goals for each content area in a convenient checklist format. A must for any health care professional involved in treating patients with diabetes. Softcover; 48pp.; #PEGDE
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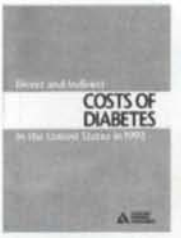

Takes a hard look at the economic impact of diabetes on our nation. If $90 billion seems like a lot to you, then you need to get this book. That's how much diabetes cost this country in medical expenses and lost productivity from premature death and disability in a single year. Softcover; 32 pp.; #PMDIC92
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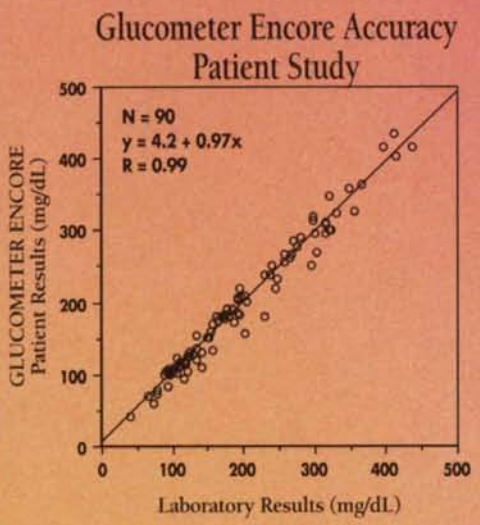

A recommendation to remember.

The GLUCOMETER ENCORE System is compact and easy to carry, and comes with everything your patients need to start blood glucose testing. Recommend the blood glucose meter that delivers a better all-around performance at a price your patients can afford. Demand an Encore.

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This quarterly newsletter highlights Professional Section events and other ADA news.

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___ Nutrition (NU)
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J47DCPM1

Take this diabetes deficiency test

	Yes	No
1. Have patients with insulin-dependent or non-insulin-dependent diabetes mellitus been shown to be magnesium deficient?	☐	☐
2. Can glycosuria and/or diuretic use cause magnesium deficiency in patients with diabetes?	☐	☐
3. Do standard diabetes nutritional guidelines ensure adequate dietary intake of magnesium?	☐	☐
4. Do I have to worry about overdosing with magnesium supplements in patients with normal renal function?	☐	☐
5. Is there a magnesium salt of choice for patients with diabetes?	☐	☐

Read the accompanying text for the answers to this test.

Magnesium deficiency–a common problem for patients with diabetes

- Significantly reduced plasma and intracellular magnesium concentrations often observed in both patients with insulin-dependent and those with non-insulin-dependent diabetes mellitus compared with nondiabetic controls[1-7]
- U.S. RDA for Mg intake (~280-350 mg) not met in 80% of NIDDM patients following standard diabetes nutritional guidelines[8]
- Can be compounded by diuretic use and glycosuria[1,9]

Magnesium chloride–the recommended magnesium salt

- Recommended by an ADA-sponsored consensus panel to reverse Mg deficiency in high-risk patients with documented hypomagnesemia[9]
- Highly soluble[10]–provides free Mg ions for maximal absorption[11]
- Efficiently excreted in urine, unless impaired renal function is present[12]

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- Unique formulation promotes rapid, efficient absorption
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- Available without a prescription at pharmacies

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(magnesium chloride)

Efficient replenishment for magnesium deficiency

References

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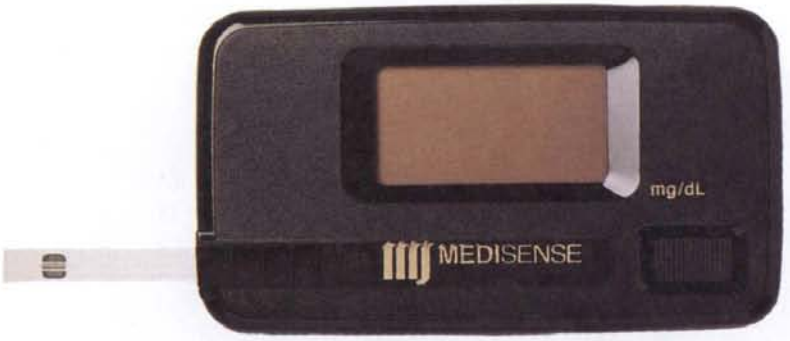

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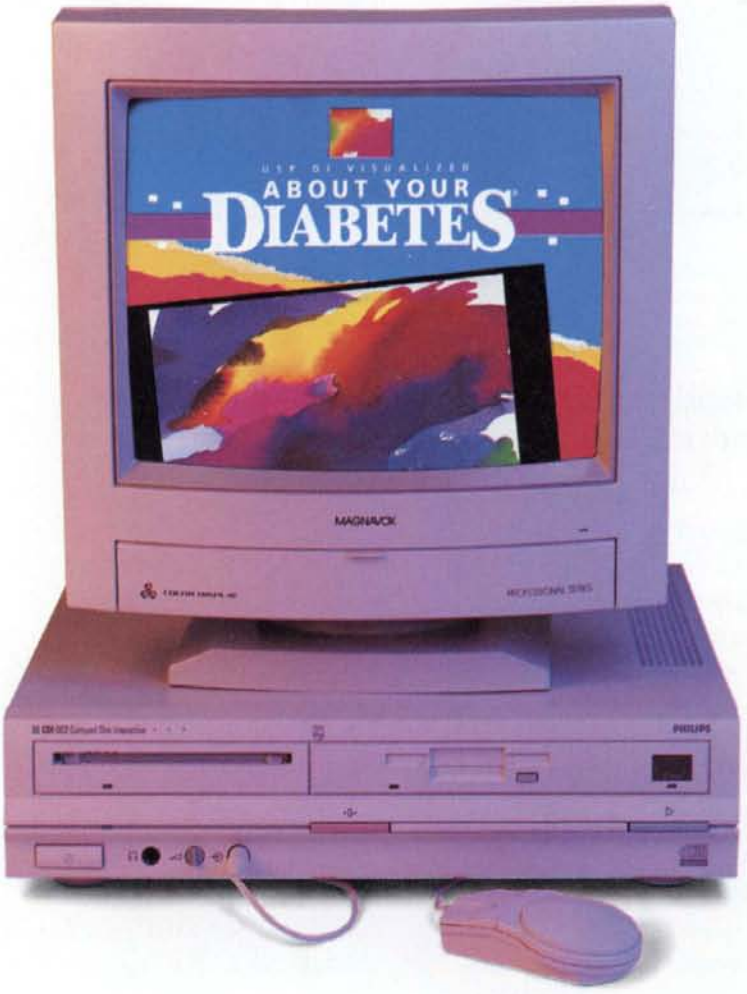

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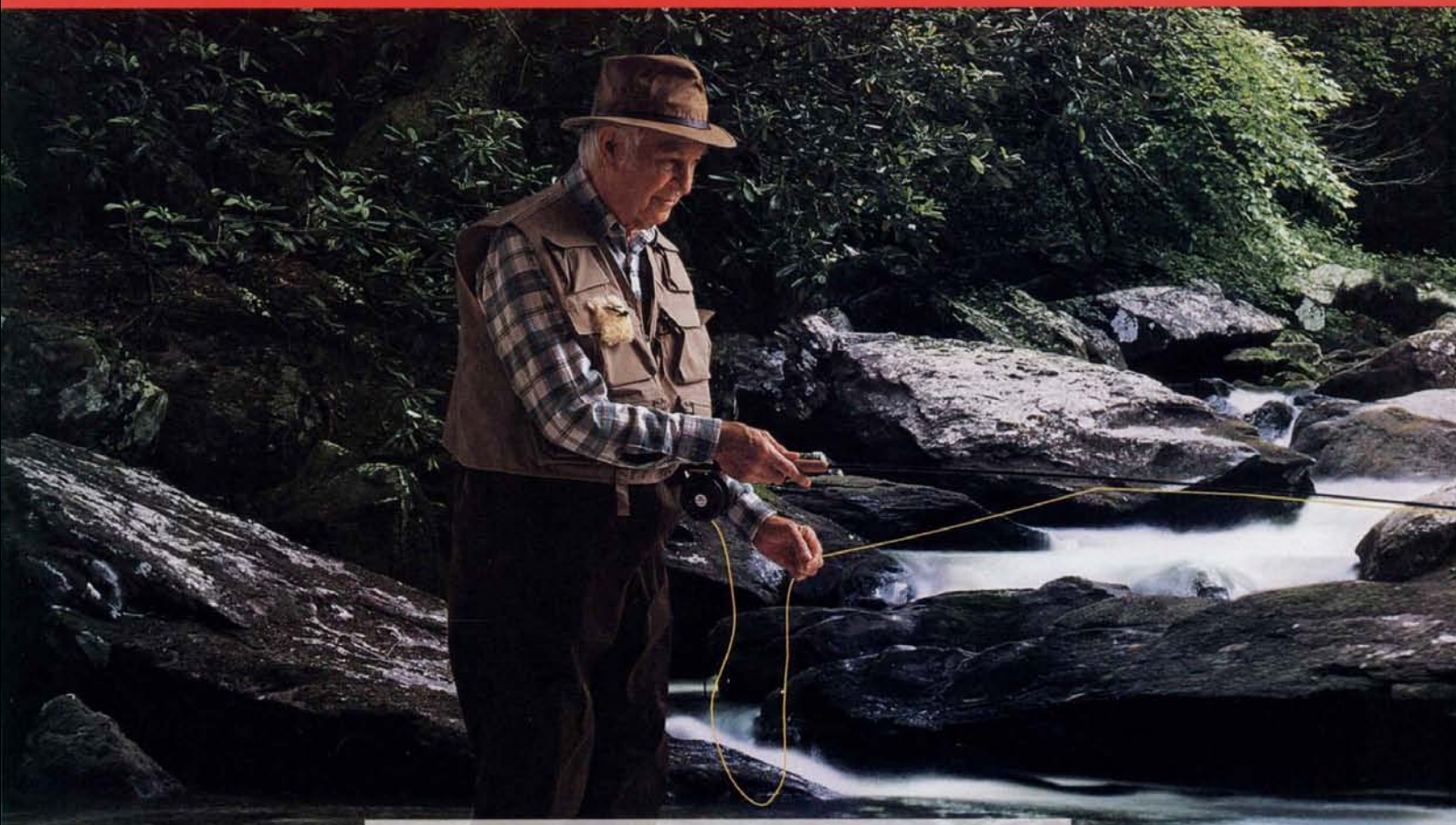

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- Proven 24-hour control in hypertension
- Proven 24-hour control in angina
- Over 1.8 billion patient therapy days reported*

EXPERIENCE THE BENEFITS

- Well tolerated
- Effective in a wide range of patient types[1-5]
- Consistent 24-hour plasma levels[6]
- No clinically significant effect on heart rate[2,3]

once-a-day

PROCARDIA XL®

(nifedipine) extended release

Tablets 30mg, 60mg and 90mg GITS

*Methodology on file at Pratt Pharmaceuticals, derived from NPA Plus™, IMS America, Ltd., 1993.

Please see brief summary of prescribing information on adjacent page .

once-a-day

PROCARDIA XL®

(nifedipine) extended release

Tablets 30mg, 60mg and 90mg GITS

TRUST THE EXPERIENCE

CONVENIENT DOSING

- Easy to titrate
- Convenient AM or PM dosing
- Can be taken with or without food

WELL-TOLERATED THERAPY

Side effects include peripheral edema, which is not associated with fluid retention, and headache

In controlled clinical trials of 776 patients with PROCARDIA XL, edema resulted in discontinuation of therapy in 2.6% of patients[6]

References: **1.** Monsen L, Moisey D, Gaffney M, Fischer J, the Nifedipine GITS Study Group. Consistent blood pressure reduction without loss of diurnal variability with once-daily nifedipine GITS treatment. *Am J Hypertens.* 1990;3(2):114A. Abstract. **2.** Parmley WW, Nesto RW, Singh BN, Deanfield J, Gottlieb SO, the N-CAP Study Group. Attenuation of the circadian patterns of myocardial ischemia with nifedipine GITS in patients with chronic stable angina. *J Am Coll Cardiol.* 1992;19:1380-1389. **3.** Phillips RA, Ardeljan M, Shimabukuro S, et al. Effects of nifedipine-GITS on left ventricular mass and left ventricular filling. *J Cardiovasc Pharmacol.* 1992;19 (suppl 2):S28-S34. **4.** Sheu WH-H, Swislocki ALM, Hoffman B, Chen Y-DI, Reaven GM. Comparison of the effects of atenolol and nifedipine on glucose, insulin, and lipid metabolism in patients with hypertension. *Am J Hypertens.* 1991;4:199-205. **5.** Reams G, Lau A, Knaus V, Bauer JH. The effect of nifedipine GITS on renal function in hypertensive patients with renal insufficiency. *J Clin Pharmacol.* 1991;31:468-472. **6.** Data on file. Pfizer Inc, New York, NY.

Brief Summary
PROCARDIA XL® (nifedipine) Extended Release Tablets For Oral Use

CONTRAINDICATIONS: Known hypersensitivity reaction to nifedipine.

WARNINGS: Excessive Hypotension: Although in most angina patients the hypotensive effect of nifedipine is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving nifedipine together with a beta-blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of nifedipine and a beta blocker, but the possibility that it may occur with nifedipine alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In nifedipine-treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for nifedipine to be washed out of the body prior to surgery.

The following information should be taken into account in those patients who are being treated for hypertension as well as angina:

Increased Angina and/or Myocardial Infarction: Rarely, patients, particularly those who have severe obstructive coronary artery disease, have developed well documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting nifedipine or at the time of dosage increase. The mechanism of this effect is not established.

Beta Blocker Withdrawal: It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning nifedipine. Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of nifedipine treatment will not prevent this occurrence and on occasion has been reported to increase it.

Congestive Heart Failure: Rarely, patients usually receiving a beta blocker, have developed heart failure after beginning nifedipine. Patients with tight aortic stenosis may be at greater risk for such an event, as the unloading effect of nifedipine would be expected to be of less benefit to those patients, owing to their fixed impedance to flow across the aortic valve.

PRECAUTIONS: General—Hypotension: Because nifedipine decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of nifedipine is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See WARNINGS.)

Peripheral Edema: Mild to moderate peripheral edema occurs in a dose dependent manner with an incidence ranging from approximately 10% to about 30% at the highest dose studied (180 mg). It is a localized phenomenon thought to be associated with vasodilation of dependent arterioles and small blood vessels and not due to left ventricular dysfunction or generalized fluid retention. With patients whose angina or hypertension is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Other: As with any other non-deformable material, caution should be used when administering PROCARDIA XL in patients with preexisting severe gastrointestinal narrowing (pathologic or iatrogenic). There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of PROCARDIA XL.

Laboratory Tests: Rare, usually transient, but occasionally significant elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted. The relationship to nifedipine therapy is uncertain in most cases, but probable in some. These laboratory abnormalities have rarely been associated with clinical symptoms; however, cholestasis with or without jaundice has been reported. A small (5.4%) increase in mean alkaline phosphatase was noted in patients treated with PROCARDIA XL. This was an isolated finding not associated with clinical symptoms and it rarely resulted in values which fell outside the normal range. Rare instances of allergic hepatitis have been reported. In controlled studies, PROCARDIA XL did not adversely affect serum uric acid, glucose, or cholesterol. Serum potassium was unchanged in patients receiving PROCARDIA XL in the absence of concomitant diuretic therapy, and slightly decreased in patients receiving concomitant diuretics.

Nifedipine, like other calcium channel blockers, decreases platelet aggregation *in vitro*. Limited clinical studies have demonstrated a moderate but statistically significant decrease in platelet aggregation and increase in bleeding time in some nifedipine patients. This is thought to be a function of inhibition of calcium transport across the platelet membrane. No clinical significance for these findings has been demonstrated.

Positive direct Coombs test with/without hemolytic anemia has been reported but a causal relationship between nifedipine administration and positivity of this laboratory test, including hemolysis, could not be determined.

Although nifedipine has been used safely in patients with renal dysfunction and has been reported to exert a beneficial effect in certain cases, rare reversible elevations in BUN and serum creatinine have been reported in patients with pre-existing chronic renal insufficiency. The relationship to nifedipine therapy is uncertain in most cases but probable in some.

Drug Interactions—Beta-adrenergic blocking agents: (See WARNINGS) Experience in over 1400 patients with Procardia® capsules in a noncomparative clinical trial has shown that concomitant administration of nifedipine and beta-blocking agents is usually well tolerated but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension, or exacerbation of angina.

Long Acting Nitrates: Nifedipine may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of nifedipine with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing nifedipine to avoid possible over- or under-digitalization.

Coumarin Anticoagulants: There have been rare reports of increased prothrombin time in patients taking coumarin anticoagulants to whom nifedipine was administered. However, the relationship to nifedipine therapy is uncertain.

Cimetidine: A study in six healthy volunteers has shown a significant increase in peak nifedipine plasma levels (80%) and area-under-the-curve (74%), after a one week course of cimetidine at 1000 mg per day and nifedipine at 40 mg per day. Ranitidine produced smaller, non-significant increases. The effect may be mediated by the known inhibition of cimetidine on hepatic cytochrome P-450, the enzyme system probably responsible for the first-pass metabolism of nifedipine. If nifedipine therapy is initiated in a patient currently receiving cimetidine, cautious titration is advised.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Nifedipine was administered orally to rats, for two years and was not shown to be carcinogenic. When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose. *In vivo* mutagenicity studies were negative.

Pregnancy: Pregnancy Category C. Nifedipine has been shown to be teratogenic in rats when given in doses 30 times the maximum recommended human dose. Nifedipine was embryotoxic (increased fetal resorptions, decreased fetal weight, increased stunted forms, increased fetal deaths, decreased neonatal survival) in rats, mice, and rabbits at doses of from 3 to 10 times the maximum recommended human dose. In pregnant monkeys, doses 2/3 and twice the maximum recommended human dose resulted in small placentas and underdeveloped chorionic villi. In rats, doses three times maximum human dose and higher caused prolongation of pregnancy. There are no adequate and well controlled studies in pregnant women. PROCARDIA XL® (nifedipine) Extended Release Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE EXPERIENCES: Over 1000 patients from both controlled and open trials with PROCARDIA XL Extended Release Tablets in hypertension and angina were included in the evaluation of adverse experiences. All side effects reported during PROCARDIA XL Extended Release Tablet therapy were tabulated independent of their causal relation to medication. The most common side effect reported with PROCARDIA XL was edema which was dose related and ranged in frequency from approximately 10% to about 30% at the highest dose studied (180 mg). Other common adverse experiences reported in placebo-controlled trials include: headache (15.8%, compared to 9.8% placebo incidence), fatigue (5.9%, compared to 4.1% placebo incidence), dizziness (4.1%, compared to 4.5% placebo incidence), constipation (3.3%, compared to 2.3% placebo incidence), and nausea (3.3%, compared to 1.9% placebo incidence). Of these, only edema and headache were more common in PROCARDIA XL patients than placebo patients.

The following adverse reactions occurred with an incidence of less than 3.0%. With the exception of leg cramps, the incidence of these side effects was similar to that of placebo alone: *body as a whole/systemic*: asthenia, flushing, pain; *cardiovascular*: palpitations; *central nervous system*: insomnia, nervousness, paresthesia, somnolence; *dermatologic*: pruritus, rash; *gastrointestinal*: abdominal pain, diarrhea, dry mouth, dyspepsia, flatulence; *musculoskeletal*: arthralgia, leg cramps; *respiratory*: chest pain (nonspecific), dyspnea; *urogenital*: impotence, polyuria.

Other adverse reactions were reported sporadically with an incidence of 1.0% or less. These include: *body as a whole/systemic*: face edema, fever, hot flashes, malaise, periorbital edema, rigors; *cardiovascular*: arrhythmia, hypotension, increased angina, tachycardia, syncope; *central nervous system*: anxiety, ataxia, decreased libido, depression, hypertonia, hypoesthesia, migraine, paroniria, tremor, vertigo; *dermatologic*: alopecia, increased sweating, urticaria, purpura; *gastrointestinal*: eructation, gastro-esophageal reflux, gum hyperplasia, melena, vomiting, weight increase; *musculoskeletal*: back pain, gout, myalgias; *respiratory*: coughing, epistaxis, upper respiratory tract infection, respiratory disorder, sinusitis; *special senses*: abnormal lacrimation, abnormal vision, taste perversion, tinnitus; *urogenital/reproductive*: breast pain, dysuria, hematuria, nocturia.

Adverse experiences which occurred in less than 1 in 1000 patients cannot be distinguished from concurrent disease states or medications.

The following adverse experiences, reported in less than 1% of patients, occurred under conditions (e.g., open trials, marketing experience) where a causal relationship is uncertain: gastrointestinal irritation, gastrointestinal bleeding.

In multiple-dose U.S. and foreign controlled studies with nifedipine capsules in which adverse reactions were reported spontaneously, adverse effects were frequent but generally not serious and rarely required discontinuation of therapy or dosage adjustment. Most were expected consequences of the vasodilator effects of Procardia. Adverse experiences reported in placebo-controlled trials include: dizziness, lightheadedness, and giddiness (27%, compared to 15% placebo incidence); flushing, heat sensation (25%, compared to 8% placebo incidence); headache (23%, compared to 20% placebo incidence); weakness (12%, compared to 10% placebo incidence); nausea, heartburn (11%, compared to 8% placebo incidence); muscle cramps, tremor (8%, compared to 3% placebo incidence); peripheral edema (7%, compared to 1% placebo incidence); nervousness, mood changes (7%, compared to 4% placebo incidence); palpitation (7%, compared to 5% placebo incidence); dyspnea, cough, and wheezing (6%, compared to 3% placebo incidence); and nasal congestion, sore throat (6%, compared to 8% placebo incidence).

There is also a large uncontrolled experience in over 2100 patients in the United States. Most of the patients had vasospastic or resistant angina pectoris, and about half had concomitant treatment with beta-adrenergic blocking agents. The relatively common adverse events were similar in nature to those seen with PROCARDIA XL.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

In a subgroup of over 1000 patients receiving Procardia with concomitant beta blocker therapy, the pattern and incidence of adverse experiences was not different from that of the entire group of Procardia treated patients (See PRECAUTIONS.)

In a subgroup of approximately 250 patients with a diagnosis of congestive heart failure as well as angina, dizziness or lightheadedness, peripheral edema, headache or flushing each occurred in one in eight patients. Hypotension occurred in about one in 20 patients. Syncope occurred in approximately one patient in 250. Myocardial infarction or symptoms of congestive heart failure each occurred in about one patient in 15. Atrial or ventricular dysrhythmias each occurred in about one patient in 150.

In post-marketing experience, there have been rare reports of exfoliative dermatitis caused by nifedipine.

More detailed professional information available on request. Revised October 1992

Pfizer

Pratt Pharmaceuticals

Beginning in July 1994, all authors must submit with their manuscripts a duality of interest disclosure statement. This form can be found in every issue of ***Diabetes*** *and* ***Diabetes Care****, along with a copyright transfer agreement. The Association has long had a policy of requiring volunteers and senior staff to disclose any dualities of interest; this form simply clarifies the nature of what must be reported and provides a uniform means of doing so. Following is the entire text of the American Diabetes Association's policy statement explaining why the Association feels disclosure is important and how it is to be implemented.*

American Diabetes Association Policy Statement on Duality of Interest

Volunteers and senior staff of the American Diabetes Association contribute to the mission of the organization in various ways. They participate on the Board of Directors, committees, and task forces, and deal with issues that have far-reaching implications. The Association is well served by the fact that many of those involved have diverse interests and are involved in a number of activities outside the Association. This interest and involvement enhances the expertise these individuals bring to the various roles they fill in representing the Association.

On occasion, however, situations arise in which an individual serving the Association in an elected or appointed position, or as a senior staff member, has a duality of interest that may be, or could be perceived as, a relevant duality of interest or even a conflict of interest. Generally, a relevant duality of interest could be said to exist when individuals have material interests outside the Association that could influence them or could be perceived as influencing them to act contrary to the interests of the Association and for their own personal benefit or that of a family member or a business associate. Most often, a relevant duality of interest is financial, such as when an individual has an employment relationship, a stock ownership interest, or a consultative or advisory arrangement, or receives a grant or stipend. In some situations a conflict of interest may exist even though the conflict does not arise out of financial considerations.

In addition, health-care professionals frequently contribute to the scientific and medical programs and activities sponsored by the Association. Such contributions are often made with support from the biomedical industry. Guidelines from the Accreditation Council for Continuing Medical Education (the continuing medical education certification body that authorizes the provision of CME credits) specifies that all contributors must disclose to the sponsoring body their relationship with the biomedical industry. Thus it is now mandatory that participants in CME events disclose all relevant dualities of interest. In addition, a similar practice is now in effect between authors and the journals and publications to which they contribute papers.

PURPOSE OF THE POLICY

A key element in monitoring relevant dualities of interest and in avoiding potential conflicts of interest is a system in which those serving the Association provide disclosure of their interests. By disclosing such interests to the Association, the Association can determine if a duality of interest is relevant and can determine the steps that should be taken to minimize the likelihood that a conflict would arise.

It is not the intent of this policy to prohibit or discourage anyone from participation in the activities of the Association. Closely related dualities of interest are not inherently wrong or bad, but the Association must be made aware of such interests in order to be able to evaluate fully their impact on the mission and activities of the Association.

SCOPE OF THE POLICY

The following categories of volunteers and staff are required to disclose to the Association any dualities of interest that may be relevant to the work of the Association:

1. members of the Board of Directors;
2. senior staff;
3. all authors, editors, and editorial board members of ADA publications;
4. all speakers/presenters in continuing medical education events, including presenters of original scientific research;
5. other members of committees and task forces whose work focuses on continuing medical education or focuses on scientific/medical issues that are of interest to the biomedical industry.

Reviewers of manuscripts need not make a formal disclosure of their relevant dualities of interest. However, reviewers are encouraged to disqualify themselves from reviewing any manuscript that deals with a matter in which they or an immediate family member has a direct interest.

TYPES OF DUAL INTERESTS THAT SHOULD BE REPORTED

The following relationships must be disclosed to the Association:

1. Employment. The name and nature of all employers must be disclosed.
2. Membership on the board of directors or any fiduciary relationship with another organization.
3. Membership on a scientific advisory panel or other standing scientific/medical committees of another organization.

4. Stock ownership. Shares of stock directly owned or controlled, including those owned or controlled by an immediate family member.
5. All consultative or advisory arrangements for which monetary compensation is received.
6. Grants/research support. Grants or research support from a company/organization whose products or services are directly related to the subject matter in a manuscript or presentation.

If relevant dualities exist for immediate family members they, too, should be disclosed.

It is obvious that all categories, conditions, or circumstances that should be disclosed cannot be listed. A reasonable test to guide decisions about what to disclose is to ask whether any particular affiliation or interest could cause embarrassment to the ADA, or to the individual or institution involved, or lead to questions about an individual's motives, if such affiliation or interest were made known.

REPORTING PROCESS

Those individuals affected by this policy must complete a Duality of Interest Disclosure Statement at the time they are appointed or elected to a new term or become officially associated with an activity of the Association as defined above (see Scope of the Policy). Thereafter a new Statement must be completed annually. Members of the staff required to complete the form will do so annually. Additionally, those completing a Statement are expected to notify the Association in writing if there are any material changes since the last form was completed. All completed statements will be kept strictly confidential.

ETHICS SUBCOMMITTEE OF THE AUDIT COMMITTEE

The purpose of this Subcommittee is to develop, approve, and evaluate the Disclosure Statement(s) used by the Association; to review the reporting and disclosure process to ensure that it is consistent with the purpose of this policy; to make regular reports to the Board of Directors to affirm that all members of the Board and senior staff have completed Disclosure Statements; to review, approve, and monitor the process and method by which there is disclosure of relevant dualities of interest in publications and programs; to provide recommendations or instructions to individuals completing a Disclosure Statement regarding actions that should or must be taken to reduce or eliminate a potential or real conflict; and to review this policy and make recommendations for revision whenever appropriate.

The subcommittee will consist of five members. The chair of the subcommittee will be appointed from the members of the Audit Committee. Two of the subcommittee members will be past officers of the Association, and two of the members will be individuals who have not participated in any activities of the Association. At least three of the members will have medical/scientific backgrounds. The members of the subcommittee will be appointed by the Committee on Councils and Committees for one staggered term of two years, and the chair will be selected from the elected members of the Audit Committee.

IF A RELEVANT DUALITY OF INTEREST ARISES

In any matter coming before the Board of Directors, committees, or a task force in which an individual has a relevant duality of interest or a real conflict occurs, the individual affected shall leave the room in which the meeting is being held and refrain from any discussions or actions on that subject. In most situations, no further action will be required. However, in some instances, the nature of the situation may require other actions be taken. The minutes of the meeting will reflect abstentions from voting due to these circumstances.

In the case of scientific/medical presentations or publications, those individuals with a relevant duality of interest will be identified in the program or publication.

DUALITY OF INTEREST DISCLOSURE FORM FOR AUTHORS OF ARTICLES IN AMERICAN DIABETES ASSOCIATION PUBLICATIONS

I have read the American Diabetes Association's Duality of Interest Policy Statement (found in the January and July issues of *Diabetes* and *Diabetes Care*), and I am indicating below that I have or have not had in the previous 12 months a relevant duality of interest with a company whose products or services are *directly* related to the subject matter of my manuscript. A relevant duality of interest includes employment, membership on the board of directors or any fiduciary relationship, membership on a scientific advisory panel or other standing scientific/ medical committee, ownership of stock, receipt of honoraria or consulting fees, or receipt of financial support or grants for research. Company is defined as a for-profit concern engaged in the development, manufacture, or sale of pharmaceutical or biomedical devices or supplies.

Each author must sign this form. (The form may be photocopied if needed.)

	Check each area that applies					
	Yes	No	Yes	No	Yes	No
Employment	____	____	____	____	____	____
Membership on an advisory panel, standing committee or board of directors	____	____	____	____	____	____
Stock shareholder Honoraria or consulting fees	____	____	____	____	____	____
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Author (please type or print)	_____		_____		_____	
Signature	_____		_____		_____	
Date	_____		_____		_____	

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I am on the board of directors of the Exacta Pharmaceutical Company, a manufacturer of pharmaceuticals related to the treatment of diabetes.

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