

*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	_____	_____	_____	_____	_____	_____
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Signature	_____		_____		_____	
Date	_____		_____		_____	

For each item checked "yes," please list on a separate sheet of paper the third-party organization with whom you have relevant affiliations or interests. Please provide sufficient information to enable the American Diabetes Association to make an informed decision. Include 1) the nature of the activity that is a relevant duality, 2) the type of financial arrangement, if any, between you and the third party, and 3) a description of the business or purpose of the third party. Please see the following sample disclosures.

### SAMPLE DISCLOSURES FOR AUTHORS

#### Employment

I am employed by Exacta Pharmaceutical Company (6250 Longwood Avenue, Any City, Missouri). My employer manufactures and markets pharmaceuticals related to the treatment of diabetes and its complications.

#### Board Membership

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

#### Stock Shareholder

I, or my immediate family, hold stock in the following companies that make products related to the treatment or management of diabetes and its complications:

XYZ Corporation

LMN Corporation

#### Honoraria or Consulting Fees

I have received honoraria for speaking engagements from the following:

XYZ Corporation

LMN Corporation

I am a paid consultant of the XYZ Corporation.

#### Grants

The XYZ Corporation is providing funds to my laboratory in order to conduct studies on a new drug to treat diabetic neuropathy.

By answering "yes" in any category, the Association will disclose the relevant duality of interest. The Association will make the disclosure by placing an asterisk by the author's name, and in a footnote describe the nature of the duality of interest, e.g., stock ownership or grant support, and the third party involved.

**This form must be returned with your submission. Make additional copies as needed for all authors. Failure to complete the disclosure may delay or prevent publication of your article.**

## COPYRIGHT TRANSFER AND STATEMENT OF ORIGINALITY

We approve the submission of this paper to the American Diabetes Association for publication and have taken due care to ensure the integrity of this work. We confirm that neither the manuscript nor any part of it has been published or is under consideration for publication elsewhere (abstracts excluded). Any reference to or use of previously published material protected by copyright is explicitly acknowledged in the manuscript.

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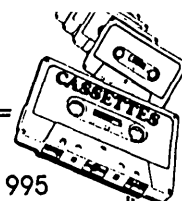
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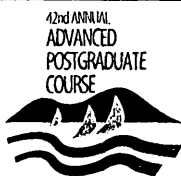
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### FRIDAY - January 20, 1995

#### GENERAL SESSION - PATHOGENESIS

- ☐ APC95-1 **Pathogenesis of Immune Destruction of the Pancreatic B-cell: Do We Know How This Happens?**, Alex Rabinovitch, MD
- ☐ APC95-2 **What Causes NIDDM: Defects in Insulin Secretion, Insulin Action, or Both?**, Simeon Taylor, MD, PhD
- ☐ APC95-3 **Diabetic Neuropathy: Is It A Metabolic or A Vascular Disease?**, Phillip A. Low, MD
- ☐ APC95-4 **Atherosclerotic Vascular Disease: Does the Pathogenesis Differ in IDDM and NIDDM?**, Christopher J. Fielding, PhD
- ☐ APC95-5 **What Causes Hypoglycemic Unawareness?**, Harry Shamoon, MD

#### GENERAL SESSION - TOPICS IN ENDOCRINOLOGY

- ☐ APC95-6 **Endocrine Hypertension Diagnosis and Treatment**, James R. Sowers, MD
- ☐ APC95-7 **Hypoglycemic Disorders**, F. John Service, MD, PhD
- ☐ APC95-8 **Evaluation of Pituitary Tumors**, Charles Abboud, MD
- ☐ APC95-9 **Growth Hormone Deficiency in Children and Adolescents: Challenges in Diagnosis and Treatment**, Alan D. Rogol, MD, PhD

#### SPECIAL PRESENTATION

- ☐ APC95-10 **Revised Standards for Diabetes Patient Education Programs**, Linda Haas, PhD, RN, CDE

### SATURDAY - January 21, 1995

#### GENERAL SESSION - TREATMENT

- ☐ APC95-11 **Can Complications in NIDDM be Prevented? If So, How?**, Saul M. Genuth, MD
- ☐ APC95-12 **Neuropathy: How Effective is the Treatment of Neuropathic Pain?**, John Griffin, MD
- ☐ APC95-13 **Nephropathy: Proven vs. Promising Therapies: Which Is Which?**, Michael W. Steffes, MD, PhD

- ☐ APC95-14 **Atherosclerotic Vascular Disease: Does Treatment of Diabetic Dyslipidemia Differ Between IDDM and NIDDM?**, M. James Howard, MD
- ☐ APC95-15 **Obesity: Can It Be Treated Effectively? What Is the Definition of Effective?**, Marion Franz, MS, RD, CDE

#### CONCURRENT WORKSHOPS

- ☐ APC95-16 **Management of Intensive Insulin Therapy in the Private Practice Setting**, Daniel L. Lorber, MD, CDE and Deborah Lagana, MSN, RD, CDE
- ☐ APC95-17 **Economics of Diabetes: Is Intensive Management Cost-Effective? And If So, How Do You Convince Third-Party Payers?**, Christine T. Tobin, RN, MBA, CDE and William H. Herman, MD
- ☐ APC95-18 **Pancreas Transplantation: What It Can't Do, What It Can Do, and What It Might Be Able to Do**, R. Paul Robertson, MD
- ☐ APC95-19 **Diabetes Management: How to Be a More Culturally Sensitive Practitioner**, Sharon Johnson, RN, CDE
- ☐ APC95-20 **The Intelligent Use of Carbohydrates: Is the Ban on Sugar Lifted?**, Sandra Gillespie, MMSc, RD/LD, CDE
- ☐ APC95-21 **1994 Nutrition Recommendations: Theory to Practice**, Melinda D. Maryniuk, MEd, RD, CDE

### SUNDAY - January 22, 1995

#### GENERAL SESSION - PREVENTION/EDUCATION

- ☐ APC95-22 **Prevention of IDDM: Is It Possible?**, Jerry Palmer, MD
- ☐ APC95-23 **Should People Be Screened for Diabetes? If So, Will It Alter the Outcome?**, Mayer B. Davidson, MD
- ☐ APC95-24 **Can Antioxidants Prevent Atherosclerotic Disease?**, Alan Chail, MD
- ☐ APC95-25 **Diabetic Foot Disease: How Do You Screen, and Can It Be Prevented?**, Andrew J.M. Boulton, MD
- ☐ APC95-26 **If Changing Behavior Prevents Disease, Can Behavior Be Changed?**, David G. Schlundt, PhD

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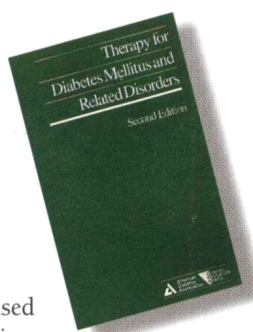
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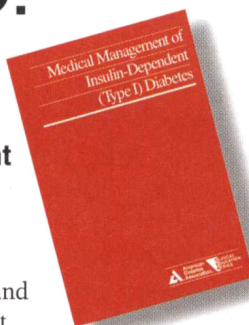


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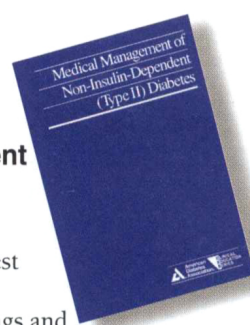


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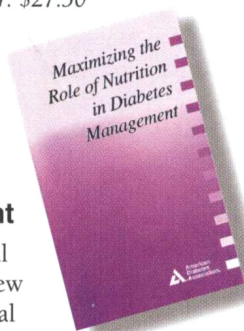
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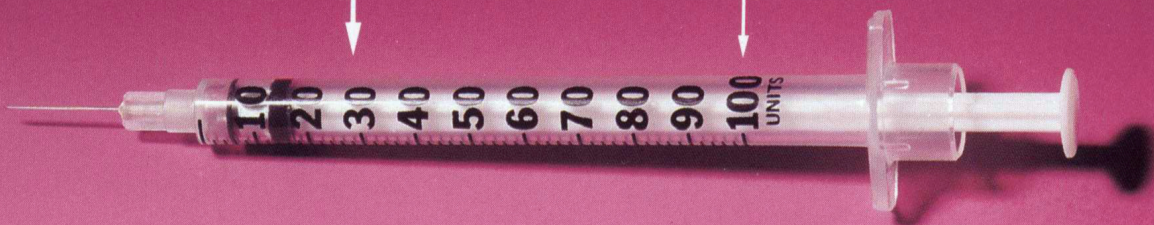
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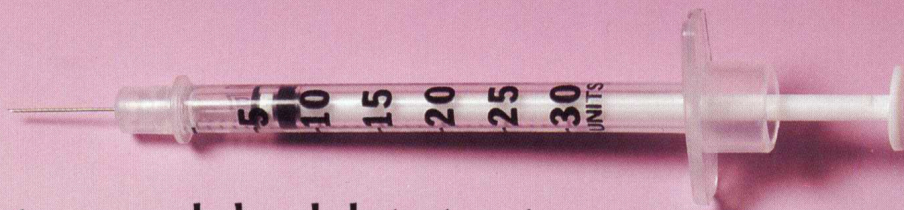


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