

This matter concerns respondents' allegedly deceptive representation that purchasers of the Investment Courses who make profitable "paper trades"—practice trades in which no funds are actually invested—using techniques described in the Investment Courses during one time period are likely to make profitable actual trades when their funds are invested in the market during a later time period. This matter also concerns the respondents' alleged failure to disclose the risks associated with the trading techniques described in the Investment Courses.

The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I of the proposed consent order prohibits the respondents from misrepresenting that purchasers of "investment courses" who make profitable "paper trades" are likely to make profitable actual trades when their funds are invested in the market. The term "investment courses" is defined as "any program, service course, instruction, system, training, manual, computer software, or other materials involving the purchase or sale of stocks, currencies, commodity futures, options, real estate through probate proceedings, or other financial instruments or investments."

Part II of the proposed consent order requires the respondents to make the following six risk disclosures:

1. For all Investment Courses: "WARNING: [FUTURES TRADING, STOCK TRADING, CURRENCY TRADING, OPTIONS TRADING, ETC., as applicable] involves high risks and YOU can LOSE a lot of money."
2. For all Investment Courses in which purchasers are advised or instructed to "paper trade" or otherwise practice making investments without investing actual funds: "Being a successful PAPER TRADER during one time period does *not* mean that you will make money when you actually invest during a later time period. Market conditions constantly change."
3. For all Investment Courses involving securities or the purchasing of options: "When investing in [securities or the purchasing of options, as applicable] you may lose all of the money you invested."
4. For all Investment Courses involving futures or the granting of options: "When investing in (futures or the granting of options, as applicable) you may lose more than the funds you invested."
5. For all Investment Courses involving futures and commodity options: "Trading in commodity futures

or options involves substantial risk of loss. According to many experts, most individual investors who trade commodity futures or options lose money."

6. For all Investment Courses in which claims are made regarding past performance: "Past Results are not necessarily indicative of Future Results."

Parts III and IV of the proposed order require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements and to provide copies of the order to certain personnel. Part V requires TWC, KRI and KRC to notify the Commission of any changes in their corporate structures that might affect compliance with the order. Part VI requires that the individual respondent notify the Commission of changes in his employment status for a period of ten years. Part VII requires TWC, KRI and KRC to file compliance reports with the Commission. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By Direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 03-7609 Filed 3-28-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Partnering Organizations for Diabetes Detection Program

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

SUMMARY: On March 6, 2003, The Department of Health and Human Services (HHS) published an announcement seeking public and private sector organizations to partner in the establishment of the nationwide Diabetes Detection Program. This notice clarifies the intent of that announcement. It describes the Program and the partnerships, which would be established through memoranda of understanding with interested organizations and entities.

ADDRESSES: Notification of interest in partnering should be sent to Elizabeth

Majestic, M.P.H., Acting Director, Office of Disease Prevention and Health Promotion, Office of Public Health and Science, Room 738-G, 200 Independence Ave., SW., Washington, DC 20201; (202) 401-6295 (telephone), 202-690-7054 (fax). Notifications may also be submitted by electronic mail to emajestic@osophs.dhhs.gov.

FOR FURTHER INFORMATION CONTACT: Ellis Davis, Office of Disease Prevention and Health Promotion, Office of Public Health and Science, Room 738-G, 200 Independence Ave., SW., Washington, DC 20201; (202) 260-2873 (telephone), (202) 690-7054 (fax), or by electronic mail to edavis@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Department will be launching a diabetes detection initiative. The goal of the initiative is to encourage people at risk for diabetes to get tested and to refer those who test positive for follow-up. Approximately 6 million people have diabetes and do not know it. It is believed that for many of these people, earlier diagnosis and management or treatment can prevent or delay the devastating complications of diabetes. State health departments and federally-funded community health centers will serve as the cornerstone for these detection efforts.

To assist the Department in implementing the diabetes detection initiative, HHS is seeking partners to participate in the initiative in accordance with their particular interests. The partnerships would be established through memoranda of understanding where each party would be responsible for resources to support their activity.

Where appropriate, organizations and entities could collaborate with state health department and community health center programs, as in the following examples:

- Partnering organizations could participate in a nationwide advertising campaign that would alert the American public to the opportunity for diabetes detection;
- Partnering organizations could participate in the production or distribution of printed materials that will be used by state programs and community health centers responsible for implementing the initiative;
- Employers could adopt the project and conduct detection clinics where people at high risk of diabetes could be identified, then referred for specific diagnosis and followup if warranted;
- Hospitals could provide professional resources to conduct detection clinics;

• Managed care plans could adopt the project and encourage their enrollees to have themselves assessed for risk and alter their lifestyles if the risk warrants;

- Colleges and universities could conduct detection events for their student populations;
- Area agencies on aging could form a component of a statewide program.

Where a statewide program is not in place, partnering organizations such as these could proceed on their own.

Availability of Funds

There are no Federal funds available for these partnerships.

Content of Request for Partnership

Each request for partnership should contain a description of: (1) The entity or organization; (2) its proposed involvement in the Department's diabetes detection initiative; and (3) resources or services the partnering organization would like to offer.

Evaluation Criteria

Partners will be selected by the Office of Disease Prevention and Health Promotion using the following criteria:

- (1) Requester's qualifications and capability to contribute to the partnership;
- (2) Requester's creativity for contributing to the diabetes detection initiative.

Dated: March 25, 2003.

Elizabeth Majestic,

Acting Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 02N-0475]

Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection"

AGENCY: Office of the Secretary, Office of Public Health and Science, HHS.

ACTION: Notice.

SUMMARY: The Office of Public Health and Science, Department of Health and Human Services (HHS) is soliciting public comment on a draft guidance document for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." This draft

guidance document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by HHS or regulated by the Food and Drug Administration.

DATES: Submit written or electronic comments on the draft guidance on or before 4:30 p.m. on May 30, 2003. Comments on HHS guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Docket Number 02N-0475, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/comments>. All comments submitted should be identified with the docket number found in brackets in the heading of this notice. Comments received may be viewed on the Food and Drug Administration (FDA) Web site at <http://www.fda.gov/ohrms/dockets/default.htm> or may be seen in the FDA Docket Management Branch at 5630 Fishers Lane, Room 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

Submit requests for single copies of the draft guidance document to the address identified below for further information. Requests may be made by mail or e-mail. Persons with access to the Internet also may obtain the document at <http://www.fda.gov/ohrms/dockets/GUIDANCES/DGUIDES.HTM>.

FOR FURTHER INFORMATION CONTACT: Glen Drew, Office for Human Research Protections, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, (301) 402-4994, facsimile (301) 402-2071; e-mail gdrew@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OPHS is seeking comments on the HHS draft guidance for IRBs, investigators, and research institutions, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." In May 2000, HHS announced five initiatives to strengthen human subject protection in clinical research. One of these was to develop guidance on financial conflict of interest that would serve to further protect research participants. As part of this initiative, HHS held a conference on the topic of human subject protection and

financial conflicts of interest on August 15-16, 2000. A draft interim guidance document, "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection," based on information obtained at and subsequent to that conference was made available to the public for comment on January 10, 2001. This document will replace that draft interim guidance.

The draft guidance recommends consideration of approaches and methods for dealing with issues of financial interests under the HHS human research subject protections regulations, 45 CFR part 46 and 21 CFR parts 50 and 56. The draft guidance expressly does not address regulatory requirements designed to enhance data integrity and objectivity in research found in 42 CFR part 50, subpart F, 45 CFR part 94, and 21 CFR part 54.

The draft guidance recommends that, in particular, IRBs, institutions engaged in research, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. The guidance poses general considerations in evaluating financial relationships and their possible effects on human subjects. More detailed points for consideration are also offered for institutions, IRBs, and investigators.

II. Request for Comments

OPHS is distributing this draft guidance document for public comment. The Secretary is interested not only in reactions to the Guidance in general, and specifically the Points for Consideration, but also wishes to solicit views and ideas as to how to best assess any impacts of this guidance, as well as related non-Federal recommendations on enhancing the protection of human subjects. HHS guidance on consideration of financial interests in human subjects research will be issued after the public comments have been considered.