

MEMORANDUM

TO: All NIH Employees

FROM: Director, NIH

RE: New Ethics Regulation

Effective upon publication in the coming days, the Department of Health and Human Services (DHHS) with the concurrence of the Office of Government Ethics (OGE) (www.oge.gov) has issued a new supplemental ethics regulation that will affect all NIH employees. You may find a copy of the regulation at http://www.nih.gov/about/ethics_COI.htm. The Federal Register notice contains both a preamble, which describes the provisions, and new rules that are applicable to all federal NIH employees. As was the case in the past, the rules apply to non-FTE personnel to the same extent the prior rules applied. This regulation is critical to restoring the integrity of the NIH and the public trust, and I fully support it.

Attached is a summary of the regulation to help you understand its key elements. We are in the process of planning training sessions to explain fully how this regulation will affect you, and we will answer all of your questions at that time. We are also currently developing several sets of procedures to implement the regulation, and we will share them with you as soon as they are completed. I encourage you to review the summary, and to plan to attend a training session, once they are announced. I would also like to emphasize the following points about the regulation:

- This new regulation focuses on three areas of the ethics program: outside activities, prohibited financial holdings, and awards. While the rules regarding these three areas will change significantly, some things will not change. For example, you will still be required to request prior approval to engage in most outside activities.
- This is an interim final regulation. This means that the regulation will go into effect immediately upon publication, and all of its provisions remain in effect unless changed by subsequent regulations. You may submit comments on the regulation as directed in the Federal Register announcement. As noted in the preamble to the regulations, the Department of Health and Human Services (DHHS) intends to evaluate certain provisions in the rule, including those regarding outside activities and financial holdings, within the next year. DHHS will consider the comments submitted and the knowledge gained from the first year of implementation when deciding what, if any, provisions to revise. We will of course notify you if any changes are made to the regulation.
- You will note that the regulation sets out broad prohibitions regarding outside activities, holdings, and awards. For example, with respect to outside activities,

all NIH employees are prohibited from engaging in certain outside employment with: 1) substantially affected organizations (generally defined as pharmaceutical and biotechnology companies); 2) supported research institutions (generally defined as NIH grantees and contractors); 3) health care providers and insurers; and 4) related trade, professional or similar associations. After general prohibitions such as these, the regulation in several sections then sets out general or specific exceptions to the provision. For example, while the regulation prohibits employment with the four groups noted above, there is an exception that may permit an employee to engage in clinical practice with a health care provider (e.g., a hospital) or to give a lecture as a part of a Continuing Medical Education program at a grantee institution. We will provide additional guidance regarding these important exceptions to the broad rule in the training sessions.

- The regulation will require many NIH employees (those who must file public or confidential financial disclosure reports), their spouses, and their minor children to sell stock owned in pharmaceutical, biotechnology, and other companies involved in research, development, or manufacture of medical devices, equipment, preparations, treatments or products. All other employees and their spouses and minor children will only be able to own up to a *de minimis* amount of stock in such companies. The regulations do make exceptions for certain types of financial interests and certain individuals or classes of individuals. You will have several months within which to sell the prohibited holdings, during which time you may seek an exceptional circumstances exception to this provision or apply for a special tax document that will allow for the deferral of any capital gains tax owed as a result of the sale of the stock. In the near future, we will issue further guidance on who is affected by this rule and how, the exceptions to the rule, and requests for deferral of capital gains tax.

I strongly believe that this regulation and all of its provisions are necessary and will strengthen the programs and operations of the NIH. It will also help us regain the public's trust that has eroded because of the actions of a few. I look forward to working with you and appreciate your cooperation as we implement this regulation.