

period of the PHS award: reporting on an annual basis any changes in the previously reported financial interests; or requiring investigators to update disclosures as new reportable Significant Financial Interests are obtained. An annual reporting requirement would serve as a reminder for investigators to review their prior disclosures, but it might be burdensome if in fact there are no changes and it could result in delayed reporting as compared to the alternative. This burden would be eliminated by the other reporting alternative, but there would be no annual reminder to investigators to review and update their disclosures. The weighing of these factors and the decision are left to the institutions. The reference to "new reportable Significant Financial Interests" is intended to include financial interests that become reportable due to an increase in value that meets the reporting threshold, as well as the acquisition of new interests that are reportable. Of course, both types of interests are subject to disclosure by the investigator only if they meet the criteria in § 50.604(c).

It was recommended that the requirement in § 50.604(g)(2) for the reporting to the PHS Awarding Component of the existence of a conflicting interest be changed to conform with the NSF approach that requires such reporting only "if the institution finds that it is unable to satisfactorily manage an actual or potential conflict of interest." As stated in the NPRM, section 493A of the Public Health Service Act requires that institutions report conflicting interests for clinical research projects. To avoid disparate requirements for clinical and nonclinical research, the regulations apply this reporting requirement to all PHS-funded research.

5. Section 50.606

One commentator felt that the notification required in paragraph (a) should go to HHS, rather than to the PHS Awarding Component. Because PHS Awarding Components are responsible for the award and have delegated authority, it is appropriate for those components to receive notifications and to act on them. On the other hand, paragraph (b) refers to HHS inquiries into institutional procedures and actions because such audit type activities may be conducted by HHS components other than the awarding agencies. As is made clear in the definitions, the term HHS encompasses all components of the Department, including the PHS Awarding Components.

A number of commentators objected to the requirement for submission of records to the HHS, fearing that the confidentiality of such records could not be assured. 45 CFR 74.53 already gives the HHS a right of access to all records pertinent to grants, which would include the records relating to financial conflicts of interest of investigators carrying out the PHS-funded research. It is expected that the PHS funding agencies will not often require the submission of records or retain copies from audits at the institution, but when that occurs the records will be maintained confidentially. In addition, although a few commentators objected to the reference to suspension of funding pending the resolution of a conflicting interest determined by the PHS awarding agency as biasing the objectivity of the research, that provision has been retained and a reference to the regulatory authority for the suspension has been added. Such suspension action would be necessary to protect Federal funds only in unusual situations, but we believe awardees subject to the regulations should be notified of the potential for such action.

Responses to Questions on Alternatives

The NPRM requested specific comments on the following issues: (1) Whether the regulations should address institutional conflicts of interest, as well as individual conflicting interests and, if so, how; (2) what types of financial interests should be disclosed; (3) whether the disclosed financial interests should include financial interests in products that would compete with the product or potential product of the PHS-funded research; (4) whether an employee's equity or other nonsalary financial interests in an applicant institution should be excluded from the definition of Significant Financial Interest; and (5) whether there should be an exemption for all compensation other than that tied to the outcome of the research. Most of the commentators addressed at least some of these issues. Those comments are summarized below.

Institutional Conflicts

Those addressing this issue were nearly unanimous in concluding that the regulations should not address the institutional conflict of interest issue because of the need to carefully consider that issue through a separate process. We agree with that conclusion. The comments on the alternatives for addressing institutional conflicts of interest will be considered separately from this rulemaking.

Competing Products

Over 30 commentators opposed any requirement for disclosing financial interests in entities or products that would compete with the PHS-funded research. Twelve commentators supported investigator disclosure of such competing entities or products, but some felt that the disclosure should be limited to those financial interests in competitors or competing products known to the investigator. As revised, the regulation would not specifically require the disclosure of such interests, but, depending upon the circumstances, those interests might come within the definition of the financial interests that must be disclosed. In clinical research, it is probable that a financial interest in a product that competes with the product being evaluated could reasonably appear to be affected by the PHS-funded research. Such a relationship is much less probable where the PHS funding is for basic research.

Types of Financial Interests Disclosed

Most of the comments on this issue are summarized above in the discussion of comments on the definition of Significant Financial Interests and on the financial interest that must be disclosed. The financial interests to be disclosed must be known to the investigator and determined by him/her to be a financial interest that would reasonably appear to be affected by the PHS-funded research or to be a financial interest in an entity whose financial interest would reasonably appear to be affected by the research. This criterion would, in most cases, require that the financial disclosure be relevant to biomedical research or health care, as was recommended by one commentator, but the disclosure would not necessarily be limited to those fields, because other types of financial interests could reasonably appear to be affected by the PHS-funded research.

Exclusion of Financial Interests

There were few specific comments on the questions relating to the exclusion from the definition of Significant Financial Interest of equity interests in, or compensation from, the applicant institution. The general comments on the definition emphasized the need for limiting disclosures to financial interests related to the research proposed for PHS funding. We are retaining the exclusion for all remuneration paid to an investigator by an applicant institution and the exclusion of any ownership interest in the applicant institution if it is an