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SPECIAL ALERT

HHS Publishes Regulations Prohibiting Many Outside Activities By NIH Employees

On February 3, 2005, the Department of Health and Human Services published regulations that substantially affect the relationship between employees of the National Institutes of Health ("NIH") and outside entities by requiring NIH employees to sever financial relationships that may create actual or potential conflicts of interest. 70 Fed. Reg. 5543 (2005). In particular, the regulations will bar many types of professional consulting arrangements between NIH researchers and outside entities, including manufacturers and research institutions that receive NIH funding. These new regulatory restrictions will require significant restructuring of many manufacturers' research and development programs.

HHS's Rationale for the New Regulations

The regulations, which take effect immediately, are a response to reviews of existing policies by both NIH and Congress. In the preamble to the regulations, HHS explained that changes were needed to avoid any appearance that the actions of NIH employees may be influenced by either private interests or loyalty to an outside employer. Some of the troublesome relationships have involved NIH researchers that have accepted consulting fees or stock options from private industry, without disclosing that relationship to the public. Several of these researchers then either wrote articles for scientific journals or spoke at professional conferences promoting that manufacturer's product and the researcher's NIH affiliation. In another case, a NIH researcher was working on an NIH-approved cooperative research project with a company, but also accepting consulting fees from that company's competitor.

The new regulations amend existing standards of ethical conduct for employees of the Department of Health and Human Services, which were first published in 1996. Those regulations generally barred HHS employees from outside employment involving either the preparation of a grant application to the agency, or in activities funded by the agency. However, the prior regulations contained no restrictions on consulting or other employment by NIH researchers. By contrast, the new regulations will prohibit many forms of employment outside of NIH and holding or acquisition of financial interests in companies that may have dealings with NIH.

Overview of the New Regulations

As of February 3, 2005, NIH employees may not accept employment (whether or not any compensation is involved) with or for the following entities:

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- substantially affected organizations, which include pharmaceutical and medical device companies, biotechnology companies, and other entities involved in the research, development, or manufacture of items and services used to furnish health care;
- health care providers, such as hospitals, skilled nursing facilities, or rehabilitation facilities;
- health insurers or health maintenance organizations;
- health, science, or health research-related trade organizations, professional associations, or consumer or advocacy groups; and
- educational institutions or non-profit independent research institutes that are or recently were NIH funding applicants, grantees, contractors, or cooperative research and development agreement ("CRADA") partners.

The scope of prohibited employment includes consulting and advisory services to an entity outside of NIH, serving as an officer or director of an outside entity, and compensated teaching, speaking, writing, or editing for any of the organizations described above.

The regulations contain six exceptions, which include teaching in a college or university, teaching or speaking as part of a continuing medical education program, furnishing health care services in a clinical or health-related professional practice unrelated to NIH responsibilities, and employment with political, religious, social, fraternal, or recreational organizations. In addition, NIH employees will not be barred from writing or editing for peer-reviewed scientific journals or texts even if they receive funding from substantially affected organizations, as long as the company's financial support is unrestricted and the company cannot exercise any editorial control. Any permissible outside activity is still subject to prior approval by NIH.

Under the new regulations, any prohibited employment relationship must cease within 30 days of the effective date. At the discretion of the NIH Ethics Office, one extension of up to 60 days may be requested.

In addition to the new restrictions on outside employment, the new regulations also limit other forms of financial relationships between NIH employees and private industry. The agency explained that many NIH employees have access to confidential commercial information and trade secrets, and the abuse of that information may have serious financial and public health consequences. As a result, NIH employees who file public financial disclosure reports, which include many senior researchers, must completely divest their holdings (and holdings in the name of any spouse or minor child) of any financial interests in pharmaceutical, medical device, and biotechnology companies within 150 days of the effective date of the regulations. All other NIH employees may continue to hold these investments, subject to a cap of $15,000 in stock provided that there are no other conflicts

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with their employment. This prohibition does not apply to stock acquired by an employee through a pension plan or other employee benefit obtained from a substantially affected organization prior to the employee's government service. In addition, the regulation exempts investments in pharmaceutical, medical device, or biotechnology companies that are part of a diversified mutual fund or a mutual fund that concentrates on non-health care companies; investments in health care sector mutual funds would still be prohibited.

The new regulations also address other forms of outside compensation, such as awards and gifts received by senior NIH employees in their official capacity. The regulations bar these employees from accepting awards valued at more than $200 provided by a donor that has matters pending before the employee as part of his or her official responsibility, or before individuals who report to the recipient.

Impact on Manufacturers and Research Institutions

Due to the broad scope of the new regulations and the short time frame for compliance, organizations that have employment or financial relationships with NIH employees should take prompt steps to determine which arrangements no longer comply with the new regulations and develop plans to close them out as smoothly as possible.

* * *

If you would like additional information regarding this topic, please contact Robert E. Wanerman, in the firm's Washington, D.C. office at 202/861-1885, or the Epstein Becker & Green attorney who regularly handles your legal matters. Mr. Wanerman's email address is rwanerman@ebglaw.com. For further information about Epstein Becker & Green's National Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

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