FDA Issues New Rules and Clarifies Its Policies on Charging for Investigational Drugs

The Food and Drug Administration (FDA) today published revised regulations, effective October 13, 2009, on when sponsors of clinical studies can charge for investigational drugs used in those studies. In addition, FDA explained some related policies. The principal elements of the revised rules and clarified policies include the following:

- In general, sponsors are prohibited from charging for investigational drugs used in a clinical trial under an investigational new drug application (IND). The prohibition applies both to unapproved drugs and to the sponsor's own approved drugs that are being investigated in some manner (*e.g.*, to obtain a new indication or an important labeling change).
- FDA clarified a point of substantial confusion by stating that the charging prohibition applies when the sponsor is using its own approved drug as an active control or in combination with an investigational drug. FDA views such uses as investigational uses of the approved drug.
- Sponsors can charge for approved drugs used for their approved purposes in a clinical trial if the drugs are obtained from an unaffiliated entity. Thus, a sponsor can charge for another company's drugs when they are used as an active control or as part of a combination with an investigational drug. Ordinary insurance reimbursement mechanisms can be used.
- In limited circumstances, FDA may authorize the sponsor of a clinical study to charge for the sponsor's own investigational drug. The sponsor must demonstrate that: (1) the drug offers a potential significant benefit over available products; (2) data from the trial would be essential to FDA approval; and (3) without charging for the drug, the sponsor would not conduct the trial because of the "extraordinary" cost of the drug. FDA will consider the resources available to the particular sponsor in evaluating whether the cost would be extraordinary.
- FDA will apply a much more liberal test with respect to drugs in expanded access programs (under which unapproved drugs are made available to patients not enrolled in clinical trials). In expanded access programs, FDA will allow charging if charging will not interfere with developing the drug for marketing approval. FDA indicates that this test will be easier to satisfy in the case of an expanded access program for a single patient or an intermediate-size patient population than in the case of a larger-scale expanded access program like a "treatment IND." (On August 13, FDA also issued regulations setting forth its approval standards for the various types of expanded access programs.)
- If FDA authorizes a sponsor to charge for its own investigational drug, the amount of the charge will be limited to the "direct" costs of manufacturing it (or purchasing it from another source) and shipping. For expanded access programs, certain administrative costs could also be included in the charge. The costs of research, development and constructing a facility for commercial production cannot be considered.
- The rules on charging for investigational drugs do not apply to IND-exempt trials. Sponsors can charge for drugs used in IND-exempt trials.

- In a preamble statement, FDA clarified that approved drugs used in clinical trials for their approved purposes can use their ordinary commercial labeling and do not require the special investigational-drug label required under pre-existing regulations.

For more information on charging for investigational drugs, please contact your Ropes & Gray attorney or any one of the attorneys from the Ropes & Gray Life Sciences practice group.