Case #1: Drug Companies Funding FDA Research

Since 1971, the Food and Drug Administration (FDA) had shown interest in charging "user fees" as a way to speed their review process and augment their funding provided by Congress. In 1992, Congress passed the Pharmaceutical Drug User Fee Act (PDUFA), which allowed the FDA to charge drug manufacturers a "user fee" to provide funds for FDA reviewers to complete their reviews within 12 months. The median drug review time was approximately 33 months in the early 1990's, which drug companies and patients awaiting new life-saving drugs, believed was too long. HIV and AIDs patients were pushing for opportunities to move new drugs more quickly through the long approval process. Soon after the PDUFA went into effect, the average review time dropped from 33 months to less than 12.

In addition to the user fees, the majority of the research on new pharmaceuticals is performed by the pharmaceutical companies themselves. The FDA engages a 12-step process in the approval of new pharmaceuticals; both the initial preclinical trials (those not performed on humans) and later human testing are performed either by the pharmaceutical companies themselves or by subcontractors for the pharmaceutical companies. After preclinical trials, the FDA orders local institutional review boards (IRBs) to determine the procedures (including dosage, measurement, and informed consent) required for human testing of a given drug. After 3 stages of human testing, FDA officials then review the results provided to them by the pharmaceutical companies in several steps in order to ensure product safety. The user fees are aimed at speeding the review process, by providing greater resources to the FDA so they can complete the reviews in a timely manner.

User fees, combined with the 12-step approval process, are aimed at providing safe, but quick approval of new medications. Those who oppose drug manufacturers paying for quick drug reviews fear that reviews conducted to meet a specific deadline risks having errors and believe that the practice gives control over FDA to the pharmaceutical companies. Additionally, critics of the FDA approval process have long noted the conflict of interest created when drug companies provide the information upon which approval of their own drugs is based. Marcia Angell, editor in chief of the New England Journal of Medicine from 1999 to 2000 believes "oversight of clinical trials is too important to leave in the hands of drug companies and their agents."

The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association for the drug industry, believes strongly in the process and supports the use of IRBs as a safe method to move along the approval process and save sick patients awaiting new drug options. "The vast majority of clinical trials conducted in the United States meet high ethical standards. The U.S. regulatory system is the world's gold standard, and the Food and Drug Administration has the best product safety record."