Mechanisms that the federal drug administration has to protect the population fro...

Law

If it finds the firm violating the law, the agency encouraged the offending company to intentionally correct the problem of recalling the faulty product from the market. Lastly, since numerous drugs are being produced by drug manufacturing firms, the FDA has accelerated the reviewing process of the drugs. This makes consumers have a variety of drugs for their ailments (Harmon, 2002).

The conflict between drug manufacturers and FDA in randomized controlled trials

The drug manufacturers argue that the randomized controlled trials (RCT) are expensive. This affects the per capita gross domestic product. Besides, it is very expensive to maintain RCTs for several years or decades. The RCTs takes several years before its findings are published. By the time the results are out, it may not be relevant in some areas (Mathews, 2006, p. 62). Even though the FDA has reduced the reviewing period, the overall length of the clinical trials has not reduced. Studies have shown that accelerated approvals of drugs discourage the completion of the clinical trials along with the safety of the drug.

Jadad (2008) argues that RCTs are not a panacea to answer all clinical questions. For instance, the effect of a risk factor like smoking cannot ethically be addressed with RCTs. Additionally, in numerous situations, RCTs are not necessary or appropriate to assist solve important problems such as cancer screening, a situation in which the outcome is rare and occurs only after a long delay. Therefore, RCTs, are not suitable for the evaluation of

interventions with rare outcomes or the effects taking an extended time to manifest.

The impact of the Prescription Drug User Fee Act (PDUFA) on maintaining drug safety in the United States

The PDUFA has enabled FDA to make new drugs available to those who are in need, as well as the capability to balance patient access against patient safety by collecting the fees from drug producers to fund the process of new drugs approvals. Thaul (2008) asserts that PDUFA funds have enabled the FDA to increase the number of new drug reviewers by 77%.