

A Bad Situation Gets Worse

FDA stands for Food and Drug Administration. This government body has a wide range of responsibilities. As its name implies, it is responsible for both the safety of our food supply and the safety of the drugs some of us take. It also regulates the safety of medical devices and surgical implants.

Recently, health care experts have criticized this body for its inability to effectively monitor the safety of drugs. The criticism was primarily directed at its post-approval safety monitoring procedures.

Most drugs that are approved have had only a relatively short study period prior to approval. The recent criticism is that harmful side-effects may take years to develop, long after the study period has concluded. The drug industry has little interest in lengthening the study period. Studies cost money and the longer the study the more money it costs. On top of that, for a block buster drug, these companies can make billions before the harmful effects are discovered. If the drug is later removed from the market, at the very least the company has made a significant profit prior to the removal.

According to experts, roughly half of all approved drugs have serious side effects that are not known prior to approval. That is a huge number of drugs that in many cases would not have been approved if the studies were longer. Vioxx is one example. It is a drug that was supposed to be a safer and a more effective alternative to other anti-inflammatory drugs that typically caused damage to the stomach. It was approved by the FDA and used by millions before it was discovered that it caused heart attacks and strokes.

Now this situation is going to get even worse. A new Supreme Court ruling prevents patients from suing medical device makers from any harm caused by their devices. The court's position was that if the device was approved by the FDA, then the FDA has accepted the responsibility for the safety of the device. Unfortunately it is much more difficult to sue a government agency than it is to sue a private company.

A number of experts believe that it is only a matter of time before the producers of harmful drugs receive the same government protection. With this protection in place, pharmaceutical companies could produce any number of dangerous drugs that only have to appear safe during the limited study period and they will be forever protected from law suits when the dangers finally surface.

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