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The FDA: Paper Tiger Or Overzealous Regulator?

The Food and Drug Administration (FDA) is currently a very bruised, battered and bewildered agency. A Harris Interactive/Wall Street Journal poll published in May 2006 indicates that the public is losing confidence in the FDA's ability to ensure the safety and efficacy of prescription medications. Consumer advocates are saying that the FDA is doing too little to remove unapproved drugs from the market. To make matters worse, the agency is facing increased scrutiny over how it handled a clinical trial testing the antibiotic Ketek in children that was halted in the spring of 2006.

The FDA is not without its defenders. Robert Goldberg, PhD of the Center For Medicine in the Public Interest and co-author of the blog Drug Wonks, has regularly taken critics of the FDA to task on a range of issues, including clinical trial design and drug safety.

A key question many are considering is whether the FDA is a paper tiger, or an overzealous regulator. Following is an overview of both sides of this issue.

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The FDA As Overzealous Regulator: The FDA's Drug Approval Process

According to researchers at Tufts University, drug makers spend an average of \$802 million to develop a new medication. A decision by the FDA can determine whether a company recoups its investment.

Well-aware of the agency's power to make or break a medication, critics assailed the FDA for taking too long to approve new medications in the 1980s. In response, Congress passed the Prescription Drug User Fee Act in 1992. Under this legislation, drug makers are required to pay a fee to the FDA to defray the costs of approving new medications.

Some critics of the FDA feel that it does not use its power to approve or deny medications appropriately. One prominent example is the debate over the "Morning After Pill." Women's health advocates wonder why the agency has not approved the medication for over-the-counter use. They ask: What is driving the FDA's decision-making? Is it politics or science?

The FDA As Paper Tiger: Drug Safety

The withdrawal of Vioxx and other medications from the market sparked a firestorm of criticism of the FDA. Critics asked: Did the agency do enough to ensure that these drugs were safe and effective? What is the agency doing to track drug side effects post-approval?

The FDA responded to critics by announcing plans to form an independent board to oversee the agency's handling of drug safety issues in 2005. However, some have said that the board is not effective, partly because it holds closed-door meetings. In a February 2006 analysis published in *Newsday*, Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania, said that closed meetings are "not good public policy." In the same article, FDA drug reviewer David Graham asserted that the board was another example of "one of several deceptive moves by FDA management to try to convince Congress that it's capable of reforming itself."

The FDA As Overzealous Regulator: Let The People Decide

Some patient advocates with rare (orphan) diseases and certain types of cancer, such as Multiple myeloma, which affects 63,000 people per year, have wondered why the FDA has been slow to allow them to take experimental medications. (In certain cases, the FDA will approve the use of unapproved medications outside of clinical trials. However, securing permission is difficult.)

Despite the dangers associated with taking unapproved drugs, some patients and their caregivers are willing to take the risk. For many of these individuals, the FDA can never act fast enough to approve a medication. They want the FDA to step aside and "let the people decide."

The FDA As Paper Tiger: The FDA's Inspection Of The Tissue Industry

In June 2006, an Associated Press (AP) article stated that "a piece of fruit coming into the United States is more likely to get government attention than a ligament or heart valve taken from a cadaver and destined for transplant."

According to the AP, the FDA's inspection of companies that sell tissue has sharply declined. Inspections have sometimes come too late to prevent tainted tissue from entering the marketplace and being implanted into patients. Patient advocates are dubbing the issue of the FDA's lax oversight of tissue companies a "crisis."

Analysis

As illustrated above, issues involving drug safety, drug approval, inspections and orphan or rare diseases are highly complex. However, the question remains: Is the FDA a paper tiger or an overzealous regulator?

The truth is that the FDA is somewhere in the middle. At times, it has acted too quickly to approve a medication or clinical trial. In other instances, it has been much too conservative. What we must remember is that the FDA has – and will continue to – make mistakes. What matters is what the agency is doing about them.

One FDA staffer Envision Solutions spoke with in June 2006 put it best by saying:

“You have to remember that there is no ‘The FDA.’ The FDA is made up of [thousands of people] from the commissioner to the janitor. There is no one brain that [manages the whole enterprise]. There are many people who are trying to do the right thing. [People on] both sides need to say: We’ve made mistakes and . . . we need to do better.”

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