

Statement of Consumers Union
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On
Congressman Ed Markey's
Report on the FDA's Failure to Ensure the Safety of Rapidly Approved
Drugs
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Rep. Markey and his staff have done a remarkable job in documenting the failure of the Food and Drug Administration to ensure the safety of drugs that are rushed through the approval process. The [data](#) he presents is further evidence of the need for this Congress to make major reforms in the FDA's post market approval safety system.

It is very important that those drugs that hold the promise of helping to save lives and reduce pain and illness get to patients quickly. But this expedited approval process is done under the condition that a full review of their safety and effectiveness will be a priority for the drug company and the FDA. After all, a drug tested on a few thousand people for a few months cannot be assumed to be safe for millions of people to use over the years to come.

The public trusts that the drug companies and the FDA will ensure that those drugs approved on an expedited basis are fully tested for safety. But Congressman Markey's report shows, unfortunately, that public trust is being abused. The data shows that all too often, post-market safety studies are not started or not completed in a timely manner. His study shows that drug companies are not living up to their obligations, and the FDA is not fulfilling its responsibility to protect the public. Without completing the promised studies, the people using the drugs become guinea pigs testing the ongoing safety of the drug and exposing themselves to avoidable risks.

There is a better way. If the drug companies will not meet their obligations, the FDA must enforce post market safety requirements. Congress should require FDA authority to impose substantial fines — civil monetary penalties — when a firm gets an expedited approval and then fails to immediately start or complete safety studies in a timely manner. The FDA also must have the authority to require post-market studies on other drugs when safety issues arise.

Consumers Union, the publisher of *Consumer Reports*, thanks Rep. Markey for his leadership in exposing this major drug safety failure. Now, it is time for Congress to act.