Decelerating the Accelerated Drug System

By ACSH Staff — June 22, 2005

Are pharmaceutical companies really "laughing" because the companies haven't finished all the drug studies ordered by Food and Drug Administration (FDA)?

That ludicrous charge was leveled by Rep. Edward J. Markey (D-MA), who has claimed that drug companies are abusing the "accelerated approval" process. This process was approved by Congress and the FDA to get drugs to patients who need them, often to save lives.

Rep. Markey's beef is that the majority of pharmaceutical companies benefiting from the FDA's accelerated approval process "have not conducted the post-marketing studies that are required by law on a timely basis."

The lawmaker said, "It is outrageous...They are laughing at the FDA, and sometimes it seems as if the FDA is treating it as a joke as well."

Under the accelerated, or fast-track, program, drug companies are committed to get an approved drug to market quickly so that seniors and others can have access as soon as possible. But the companies are also required to continue studying an approved drug after it goes on the market.

Often, studies by drug companies are not completed because the FDA determines that a new protocol should be tried for administering the drug. This slows down completion of the study.

It is important to understand that the Food and Drug Program generally works quite well. It ensures that patients get safe and effective medicines tested in clinical trials. Less than 3% of pharmaceutical products have been withdrawn from the market for safety reasons over the past twenty years, according to statistics collected by the drug industry trade group, the Pharmaceutical Research and Manufacturing Association.

"There has been no change in the withdrawal rate since the fast-track approval system was implemented in 1992. The FDA's approval and monitoring efforts are considered to be the gold standard internationally," a spokesman said.

He added, "Agency officials nevertheless are working on improvements to post-marketing safety regulation." A new drug safety advisory board has been established and the Institute of Medicine has been asked to thoroughly investigate FDA drug safety.

Bill Vaughn, a policy analyst with Consumers Union, chimed in with this statement: "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...Markey’s report is further evidence of the
need for Congress to make major reforms in the FDA's post-market approval safety system."

Markey also charged that information provided by the Securities and Exchange Commission indicates that "many drug companies have not disclosed information regarding post-marketing studies to their investors." Of ninety-one post-marketing studies required by the FDA, forty-two studies have not been completed, Markey claims. (Incidentally, there is no clear legal requirement that companies have to make known this information.)

Markey is the author of legislation to set up a federal registry of all clinical drug trials, to make sure pharmaceutical companies disclose results. He said he plans to introduce new legislation to provide information to patients and doctors about "accelerated approval process" drugs and to improve FDA's capacity to oversee post-marketing studies.

His legislation would require companies to inform patients and doctors when a product has received conditional approval under the fast-track system. He would require that drug companies put on the drug’s label whether it has conventional approval or an accelerated approval. Furthermore, Markey's legislation would also establish fines of as much as $1 million a day for failure to conduct timely post-marketing studies. More costly drugs would result from inflicting these new procedures and new fines on drug companies (and fear of fines will make companies more cautious about deploying accelerated drugs). Markey is partially undoing the gains from speeding up the process of getting much-needed drugs to patients in the first place.

Tait Trussell won a Loeb Award "for distinguished reporting of business and financial news" and a Benjamin Fine award for columns on education. He was vice president of the American Enterprise Institute for Public Policy Research (AEI[1]) and served on the Bicentennial Commission on the U.S. Constitution.