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FDA's 2007 Report On Outstanding Post-approval Studies: No Progress Made By Big Pharma

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POSTED: Monday, April 28, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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After Their Medications Get Approved By FDA, Many Drug Companies Have Not Yet Started The Studies Which They Promised To Do

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

Each year the FDA issues what could be called a "report card" on how the pharmaceutical companies are doing as regards post-approval studies for their products that have been approved for sale in the U.S. As was the case the year before, in 2007 these companies are doing poorly in getting done what they said they would do.

In an April 23, 2008 *Bloomberg* article, "[Drugmakers Didn't Begin 1,044 Promised U.S. Studies](#)", reporter Justin Blum presents the facts and gets some relevant reactions.

Let's start with the continuing dismal performance by Big Pharma:

The Food and Drug Administration determined that 1,044, or 62 percent, of incomplete studies for conventional drugs and biotechnology medications had yet to be started as of Sept. 30. At the same time in 2006, 1,026, or 63 percent, of the unfinished studies hadn't begun, according to the FDA.

As background, the drug companies often agree to perform additional clinical trials evaluating the efficacy and safety of their medications in order to get the FDA's approval -- but, seemingly, their agreement is more of a promise than it is an actual commitment.

This apparent failure to get these studies done in a timely manner can be viewed in various ways, according to who you talk to about this situation. Quoting from the April 23 *Bloomberg* article, we consider these three "perspectives":

- Peter Lurie, deputy director of the Health Research Group at Washington-

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based Public Citizen, an advocacy organization: "Drugs often come on the market with an expectation that studies will be conducted. In fact, many of these studies begin late or do not begin at all."

- Alan Goldhammer, deputy vice president for regulatory affairs at the Pharmaceutical Research and Manufacturers of America, an industry group: "Studies can take a long time to begin because of discussions with the FDA over how they should be conducted and difficulties enrolling patients."
- Susan Cruzan, a spokesperson for the FDA: "The FDA is considering how to 'integrate' its new power to require studies with commitments that have been made by drugmakers. The FDA will work to ensure that studies previously promised 'are completed in a timely manner.'"

Unfortunately, like earlier versions, this 2007 FDA report does not specify the number of drugs covered by the various outstanding studies -- Mr. Blum points out in his article that "[d]rugmakers sometimes agree to complete multiple studies for a single product" -- nor does the annual report identify the specific companies involved with the many outstanding post-approval studies.

Maybe next year we will be able to tell you that the "class" has done better on this report card about their post-approval studies.

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