

Adverse drug side effects reporting is slow - then the real problem starts

By ACSH Staff — August 10, 2015



A recent [study](#) ^[1] from *JAMA Internal Medicine* found that 1 in 10

serious and unexpected drug side effects are not reported by pharmaceutical companies to the FDA within the 15-day required window specified by federal regulations to protect patient safety.

Additionally, it was found that adverse event cases reported with death outcomes had a slightly higher rate of failing to comply with the 15-day reporting window.

But that is not the biggest problem.

MedPage Today op-ed writer Brian Overstreet [argues](#) ^[2] that the most important is the delay the FDA has in releasing these data to the public: Currently, the most recent publicly available FAERS data includes case reports received by FDA through December 31, 2014. That means that critical, potentially life-saving, data is currently 7 months out of date. And we're not talking about 10% of the data being late. We're talking about 100% of the data being late. While pharmaceutical companies have a requirement to report adverse event cases to FDA in a timely manner, FDA has no such obligation to release those data to the public in a timely manner.

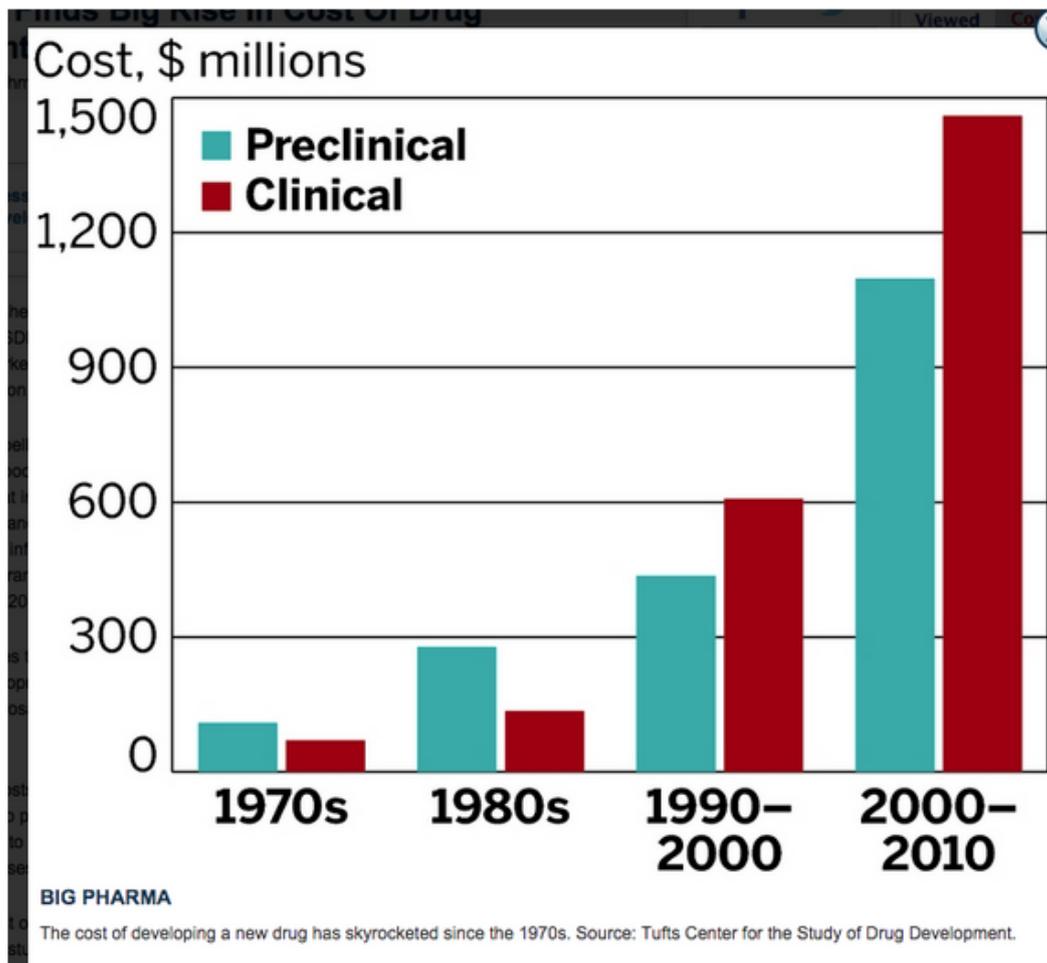
And the second real problem: it takes an average of five full years for the FDA to issue a label change after a safety signal is detected from the FDA Adverse Event Reporting System (FAERS). These, Overstreet writes, are not just problems, they're a public health disaster.

The analysis included 1.6 million side effect reports to the FDA from 2004 to 2014. Overall, 160,383 serious adverse events, or 10 percent of reports, were not disclosed by companies within 15 days including nearly 40,500 reports involving patient deaths.

Ours is the first study to empirically examine the extent of delays in reporting, said study author Pinar Karaca-Mandic, a researcher at the University of Minnesota School of Public Health in Minneapolis.

Dr. Josh Bloom, Director of Chemical and Pharmaceutical Sciences at the American Council on Science and Health says, This story represents only one of many facets of the difficulty of developing a new drug. Although the FDA is too slow releasing adverse events, they are requiring more and more clinical studies (including safety studies) before approving a new drug. This can be

inferred from the graph below, which clearly shows the very profound change in the financial burden that has been placed upon companies in just a decade."



He continues, "Although the industry is being asked to provide more and more safety data, the system is bogging down both the companies and regulatory agencies. In my opinion, this is not an attempt by companies to 'slip something by' the FDA. Rather, it is more a function of a difficult, bulky and antiquated system that is becoming more so, especially in the era of new medicine (personalized medicine), which is still in its infancy. A more focused and effective method of detecting and reporting adverse effects is needed, but this is no easy task.

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