Probe Shows FDA as Laggard in Drug Trial Follow-ups

By Gil Ross — January 18, 2016

Earlier this month, the results of an investigation of the FDA by the federal General Accountability Office (GAO) were reported, and the agency is likely to be embarrassed by its findings. Under the rubric Drug Safety [1], the report was entitled "FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement."

Beginning in 2003, the FDA set about establishing pathways for expedited reviews for new drug applications in certain categories where it was felt that the standard, multi-year process was too onerous, given urgent need or possible breakthrough drugs. The initial impetus was from AIDS activists, but the categories expanded to include numerous oncologic, or cancer-related, and infectious-disease-related concerns. The expedited reviews were covered under several "subparts," also known as "fast-track" pathways.

As per the FDA [2]: "Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Such designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)."

Generally, the approval process allowed for "surrogate" endpoints in place of definite outcomes: one example would be allowing shrinkage of a tumor in lieu of actual improved survival as a criterion for approval. Other shortcuts were also included in the fast-track paradigm. However, one major caveat for getting an expedited approval was a commitment by the drug company to continue to collect health data regarding both safety and efficacy on patients getting the expedited drug, in so-called Phase IV/post-marketing studies.
The failure of the FDA to collect those data is the focus of the new GAO report.

Findings include a litany of shortcomings in FDA’s system for tracking drug safety issues, including incomplete, outdated and inaccurate information. The FDA announced with some fanfare recently that last year they approved 45 first-of-a-kind drugs the highest number in 19 years with most reviewed in approximately eight months. While more than half received some form of specialized review to speed their path to market, it was those very items about which the GAO says the agency all-too-often failed to keep track of follow-up studies required for such high-priority drugs. The investigation revealed that the FDA was late in reviewing more than half of the 1,400 follow-up studies it had requested or required of drugmakers between 2008 and 2013. Those studies are critical for spotting safety issues that may not emerge until after patients start taking the drugs.

The report was commissioned by Rep. Rosa DeLauro, the ranking member of the House Subcommittee on Health and Human Services. The Connecticut Democrat said the findings suggest the FDA is shifting more of the safety risk to consumers. "The GAO report clearly highlights that FDA is not doing its due diligence in tracking drug safety issues and post-market studies that are critical in ensuring patient safety," DeLauro said in a statement.

The FDA also revealed to GAO investigators that the majority of potential safety issues identified by staffers had not been uploaded to its archival drug tracking system.

The Department of Health and Human Services, which oversees the FDA, said the agency is conducting internal evaluations to improve its computerized tracking system, which it acknowledged is challenging to update.

The concept of expedited drug review for urgently challenging health issues is undeniably a valuable policy, and the failings revealed in the GAO report should not be construed as a strike against those processes. Indeed, the spreading "Right to Try" movement to allow desperate patients to bypass the FDA in certain circumstances echoes that need.

But I have to admit that I found it disconcerting to find the extent of apparent negligence of the FDA in collecting important information on potentially toxic drug effects. Hopefully this report will spur rapid progress in tabulating the needed data: this seems like a valid initial project for the FDA’s new head to take on, as soon as possible.

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