


Editor’s Note

**Faster Drug Approvals Are Not Always Better and Can Be Worse**

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A shared goal of all health professionals is to relieve suffering and prolong life. At times these goals are at odds, particularly in oncology care. Patients with severe disease and low chance of survival may be offered therapies in the hope of buying a few more weeks or even months. However, the treatments themselves are often toxic, with many unpleasant adverse effects—nausea, pain, vomiting, hair loss, and others—that detract from quality of life and result in patients spending more time in the hospital and clinic and less time at home. It is a difficult choice: extend life, or offer higher quality of life at home.

Or is it? This choice assumes that the drugs really do extend life. The analysis by Prasad et al1 shows that many oncology drugs have never been shown to increase survival, meaning that patients suffer reduced quality of life but do not necessarily gain extra time. In the effort to get more new drugs on the market more quickly, many agents are approved on the basis of surrogate end points, such as progression-free survival. Unfortunately, these surrogate end points do not necessarily translate into any mortality benefits, in which case patients experience the toxic effects but do not get any extra time.

Even when the US Food and Drug Administration takes the dramatic (and rare) step of withdrawing approval (as it should when a drug approved based on surrogate markers later turns out to not offer any mortality benefit, as was the case for bevacizumab (Avastin; Genentech/Roche) for metastatic breast cancer, women continue to be treated with this harmful drug although we know it will not extend life.

The 21st Century Cures legislation2 now being considered by Congress would make this situation much worse by allowing accelerated approval of new drugs based on preliminary results of clinical trials on surrogate markers. It even has a clause that stipulates that a drug on a restricted hospital or industry formulary list is actually approved for the indication and can be prescribed for that purpose. In fact, it introduces 2 more categories of fast drug approvals. However, in 2014 over 60% of approved drugs were already approved using expedited review or orphan drug status, which also has reduced evidence standards for safety and effectiveness.3 We must reduce drug approvals based on unreliable surrogates and change practice when clinical studies show no survival benefit. If there are no drugs available that can extend life with tolerable adverse effect, we must extend warmth and compassion and support in a continued therapeutic relationship without further chemotherapy. In our rush to find new effective treatments, we should not harm our patients with ineffective toxic ones.

**Conflict of Interest Disclosures:** None reported.


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