Quick cancer drug approvals don't benefit patients, researcher says

May 7 2015

Highly priced cancer drugs get rushed approvals despite poor trial methodology and little effect on the longevity of patients, cautions York University Professor Dr. Joel Lexchin in the School of Health Policy and Management.

"Patients and their doctors should demand that regulators require pharma companies to provide clear evidence of clinical effectiveness of the drugs, resulting from rigorous methodology," suggests Lexchin. "Drug agencies like the Food and Drug Administration (FDA) and the European Medicine Agency (EMA) don't actually look at whether people live longer."

In an article in the *British Medical Journal*, titled "Why do cancer drugs get such an easy ride?", Lexchiin and co-author Donald Light, a professor in the School of Osteopathic Medicine, Rowan University in New Jersey, note that accelerated approval and shortened review times also make it a smooth sail for cancer drugs.

Lexchin cites earlier research reviewing solid cancer drugs within 10 years of EMA approval to point out that these drugs improved survival by just over a month.

"Similarly 71 drugs approved by the FDA from 2002 to 2014 for solid tumours have resulted in median gains in progression-free and overall survival of only 2.5 and 2.1 months, respectively," he says adding, "Also, only 42 per cent met the American Society of Clinical Oncology Cancer

Research Committee's criteria for meaningful results for patients."

The authors observe that pharma companies are having an easy ride with the European and US regulators, who are allowing them to test cancer drugs using surrogate measures instead of survival and other patient-centred measures.

Provided by York University