

New Study Claims Cancer Drug Trials End Too Soon

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According to recent research, the benefits of new cancer drugs are being "exaggerated" because trials are stopped too soon. The research also adds that growing numbers of pharmaceutical companies are halting trials—even including trials for the breast cancer drugs Herceptin and Lapatinib—when good interim results are received. The study warns patients could be at risk if drugs are licensed and rushed into clinics before possible side effects are fully identified.

The study—led by Dr. Giovanni Apolone, of the Mario Negri Institute for Pharmacological Research in Milan—results have been published in the journal *Annals of Oncology*. Twenty-five controlled trials were analyzed and picked at random. Each trial lasted approximately 30 months and each was ended early when results indicated patient benefit. "When we analyzed 25 trials over a ten-year period between 1997 and 2007, we found more than 50 per cent were stopped within the past three years," said Apolone. "While this could guarantee quicker access to the market for companies, it could also lead to an 'immature' evaluation of the benefit and risk balance of new drugs. We believe that only untruncated trials can provide the full level of evidence required to safely translate treatments into clinical practice," he added.

"Without such evidence, unsafe and ineffective drugs could be marketed and prescribed, and patients' health could be jeopardized," Apolone continued. Most—three-quarters—of the trials were halted when independent monitoring committees said the drugs were so successful, it would be "unethical" to deprive patients of them. "We, as scientists, put a great deal of work and effort into designing appropriate clinical trials, and in all but the rarest of cases we should not rush to abandon those designs in the face of early signs of benefit," said Professor David Kerr, editor-in-chief of *Annals of Oncology*. A spokesman for the Association of the British Pharmaceutical Industry said it strongly rejected any suggestion that commercial interests led to trials being halted early. "The interest of patients is the overriding concern," Kerr added.

But, recently, some of the United States' best selling and most heavily promoted drugs have come under fire. The popular diabetes drug, Avandia, may raise the risk of heart attack; antidepressants may work no better than placebo; and top cancer drug, Avastin, may slow breast cancer, but does not impact overall survival. Critics in the US wonder if drugs are being released to market too soon and if—instead of relying on ultimate outcomes such as a reduction in heart attacks or strokes—many studies measure a drug's effectiveness by using interim markers, such as lowered blood pressure. The Food & Drug Administration (FDA) allows such markers because the cost is prohibitive when waiting for the results of large-scale outcome trials and the waits could possibly delay life-saving advances for millions, said Dr. Robert Temple, director of the agency's office of medical policy. But the practice has been called into question, said Dr. Nortin M. Hadler, a professor of medicine at the University of North Carolina. "In our zeal to do modern medicine ... we've managed to lose our way," he said. "We've forgotten to ask: 'Does this matter to the patient?'"