The FDA's Stunning, Dangerous Decision

Patients lose with a recent vote preventing access to a promising new treatment drug

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May 10, 2013

Their decision will have a chilling effect both on future research and on clinical trial design. Given the overwhelming solidarity of the committee's vote, every major pharmaceutical company has to be asking themselves: Why would we allow crossover in our trial design? The result will be trials geared only toward data collection with less regard to patient's health – or more likely more trials conducted completely outside the U.S. – exactly what we've been opposing in the patient community.

If FDA can change the primary endpoint of trial requirements mid-stream every bio-tech company has to be asking themselves if they want to fund costly trials in the first place. None of the other kidney cancer drugs were held to the same standards in their approval process. Glaxo Smith Kline's drug Votrient was run against *placebo* and won approval.

Aveo could and should have done a better job with their trial design to ensure against anomolies. But the result is that kidney cancer patients will be denied access to a drug that provides longer progression free survival than any other drug on the market and has fewer or less severe side effects than other drugs. FDA made its point, but kidney cancer patients are stuck with explosive diarrhea.

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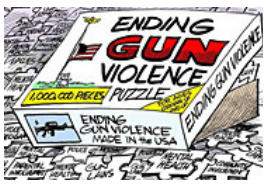

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