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Fact Sheet: Bedaquiline (Sirturo)

Would you want a treatment that killed one out of every ten patients? Few people would say "yes" to a treatment for which the available evidence showed that it killed one out of every ten patients. Yet the Food and Drug Administration did just that when it approved the new antibiotic bedaquiline (Sirturo).

Bedaquiline was fast-tracked under three existing accelerated approval programs.[1] Evidence for safety and effectiveness included just one controlled trial: a single, small, "Phase II" trial in patients with multi-drug resistant tuberculosis (TB). That trial proved that bedaquiline does eliminate live TB from coughed up sputum more quickly. But it also appeared to kill patients: ten of the bedaquiline-treated subjects died, compared to two subjects in the placebo group. If translated to clinical practice, one out of every ten patients who adds bedaquiline to existing TB treatments could die as a result.[2]

Bedaquiline could kill one out of every ten patients.

The FDA approved bedaquiline in 2012.

Because the Phase II trial was so small, bedaquiline's manufacturer was able to argue that the deaths could have been random, not caused by the toxic drug. The FDA, before approval, should have required additional evidence from a Phase III trial showing that the drug did not increase the death rate. Instead, the FDA approved the drug and ordered a large post-approval trial, which will not be completed until 2022.

Standards for new antibiotics should be strengthened, not weakened.

The 21st Century Cures Act would eliminate large, well-designed "Phase III" trails for most antibiotics, meaning more new antibiotics will be approved with potential deadly risks.

Vote "no" against the 21st Century Cures Act.

[1] Fast track, Priority Review, and Orphan-Product.
[2] Public Citizen. Letter to FDA Opposing Approval of Bedaquiline. 12/21/2012. http://www.citizen.org/hrg2088.