Could Your Cancer Meds Be Prescribed at a Less Toxic Dose?

The FDA's Project Optimus requires companies to determine the best drug doses before new medications reach patients.

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Testing new drugs and pinpointing the best dosage takes time. Unfortunately, people with cancer don't have that luxury. To get novel oncology treatments to cancer patients as quickly as possible, regulators developed an accelerated approval process. But recent evidence is revealing flaws in that process. Of note, it can result in the approval of drugs that don't extend life or in high dosages that don't show a significant benefit but do cause intolerable side effects, leading patients to skip or stop treatment.

To ensure that cancer patients receive the most effective, least toxic medication dosages, the Food and Drug Administration (FDA) launched Project Optimus to reform dose optimization and dose selection in oncology drug development.

Launched in 2021, the project stresses the importance of identifying a dose with optimal tolerability during drug development, according to Nova Discovery.

The current system for dose selection may lead to inadequate or excessive doses and schedules of chemotherapies and targeted therapies. In many cases, researchers aim to find the maximum tolerated dose, or the highest dose patients can take without unacceptable side effects. A poorly selected dose or schedule may cause increased toxicities, the FDA says.

Project Optimus was created, in part, to address the faults of the accelerated approval process that the FDA initiated in 1992, according to The Washington Post. The accelerated approval process is intended for drugs for serious conditions.

A study published in JAMA found that of 46 cancer types treated with drugs that received accelerated approval from 2013 to 2017, 19 did not result in longer survival or improved quality of

life after more than five years. What's more, a majority of cancer drugs were converted from accelerated to regular approval based on surrogate measures, not overall survival or quality of life. (Read more about this in Cancer Health here.)

Donald Harvey, PhD, a pharmacology professor at Emory University, told the Post that many drugs fail because they need to be given at toxic dosages to be effective. Identifying an appropriate dosage earlier could mean drugs might perform better.

"Instead, they followed the old model and said, 'We're going to push the dose up until we see a major side effect,'" Harvey told the Post. "They didn't need to do that. They just needed more experience with a lower dose."

In collaboration with drug companies, health care professionals, international regulatory authorities and others, Project Optimus aims to switch from the standard maximum tolerated dose approach used in oncology to one that finds the best dose to maximize efficacy and tolerability.

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