The FDA vs. Cancer Patients

The American Society of Clinical Oncology met this week in Florida, where it heard promising study results about a host of developmental cancer therapies. "Just in the last year or so there are many more options," one researcher was quoted as saying. "None of them are FDA-approved yet. Hopefully soon they will be."

Drugs that save lives belong on the market.

The bad news is that "hopefully" really is the operative word here. Former FDA Commissioner Mark McClellan made some progress moving the agency to speed up the drug approval process. But he was pulled away to run Medicare, and agency bureaucrats have since been working feverishly to turn back the clock.

The latest evidence of backsliding was a recent vote of the Oncologic Drugs Advisory Committee (ODAC) to recommend against approving Johnson & Johnson's leukemia drug Zarnestra. The drug may not be a miracle cure—15% of study patients achieved complete remission. But 15% is nothing to sneeze at either, especially since the company was seeking accelerated approval for the treatment of elderly patients who might not be able to withstand the punishment of traditional chemotherapy. Yet ODAC voted against adding this weapon to the anti-cancer arsenal.

This is a special shame because ODAC used to be a bastion of common sense, wherein clinicians who treat cancer patients would often buck FDA statisticians to approve new drugs. But ODAC is now chaired by osteopath Silvana Martino, who is notably hostile to the drug industry, and so it is unlikely to continue to be an independent check on the FDA.

A related blow for cancer patients was the selection last month of Richard Pazdur to head the FDA's newly consolidated oncology drugs division. Drs. Pazdur and Martino share the view that the FDA's mission is to force the pharmaceutical industry to jump through certain hoops as much as it is to get good drugs to patients. "The purpose of accelerated approval was not accelerated drug company profits," Dr. Pazdur says, as if the researchers whose work is coming before him are selling snake oil.

Dr. Martino, meanwhile, believes that "millions and millions of dollars are being spent looking for drugs with low efficacy"; she should tell that to patients for whom incremental progress can mean extended lives. The fear in the cancer patient community is that the doctors want to undo the accelerated approval process for all but the most obviously effective cancer drugs, even though many of the best ones only demonstrate their true worth when they are used in clinical settings.

This was demonstrated again at the oncologist meeting. Notable among the impressive drugs was Erbitux, whose original rejection by the FDA helped land Martha Stewart in jail, and which continues to look better and better as a treatment for colon cancer.

The next thing to watch for is the fate of AstraZeneca's lung-cancer drug Iressa, which Dr. Pazdur is signaling he may actually pull from the market as one of those "low efficacy" drugs. True, Iressa helps only about 10% of patients. But those who respond to it respond massively. "I've had patients who have gone from being on oxygen to skiing at altitude," says one doctor of the drug. Genetic tests are being developed to better predict who will respond to Iressa. Yet Dr. Pazdur seems to regard the FDA's Iressa approval in 2003 as an instance of the drug industry getting away with one. Incredible.

One way Congress could fight back would be with a law ending the moral travesty of placebo-controlled drug trials for terminal diseases. This has been Dr. Pazdur's main delaying tactic, justified as a way to prove efficacy beyond any doubt, regardless of how many people may die in the interim. (The oncologist conference also saw data presented questioning the value of lengthy drug trials.)

As for the White House, its failure to offer adult supervision of the FDA—an executive branch agency that regulates one-quarter of the economy—is increasingly notable and unfortunate. The agency has lacked a Commissioner confirmed by the Senate for about year; acting head Lester Crawford has been nominated for the job but is mired in the Senate's confirmation maw and in any case shows little inclination to buck the FDA culture that produced Dr. Pazdur.

Who would have thought that, five years into a Republican Administration, the FDA would be staffed by people who regard industry as an adversary, not a partner, in the anti-cancer fight.