Will the FDA's 'Drug Czar' Decide to Let My Dying Mother Suffer More?

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If you or a loved one have ever heard, from a physician, "All we can do at this point is manage your cancer," you know the terribly frightened and desperate feeling those words evoke. You immediately know that you'll do anything — anything — to change reality. You ask, perhaps beg, if there is something that can be done — even though the doctor's statement was so plain. As reality sinks in, you start to ask and learn about "managing" pain and life with terminal cancer.

I have heard those words spoken to my mother, who is living with Stage IV cancer. Life has, in some ways, become very simple for her. She has told me she wants just two things: less pain and more time.

There are drugs that can offer those things to my mother and other terminally ill cancer patients.

Unfortunately, whether they will have access to them is increasingly decided by a single individual, named Dr. Richard Pazdur, in Washington, D.C. Dr. Pazdur is known as the Food and Drug Administration's "Drug Czar." This one man can impact thousands of lives by simply re-categorizing drugs. He doesn't need approval from Congress. He doesn't need input from the public. He simply decides based on his own subjective judgment.

Shocking as it may seem, Dr. Pazdur is currently weighing whether to remove the anti-cancer drug Avastin from a list of medications available, specifically, to Stage IV breast cancer patients.

Dr. Pazdur's action won't ban Avastin entirely. There is no need for that — the drug has already met government standards for safety and efficacy and is also used to treat colon, lung and other cancers.

As reported by The Wall Street Journal, in July, "an FDA advisory panel voted 12-1 to remove the breast cancer indication from the drug's label. If the FDA follows the advice of its committee — as it often does — the drug could still be marketed to treat colon, lung and other cancers."

Dr. Pazdur says that Avastin's benefits for women with breast cancer who are dying and in unthinkable pain are just not "clinically meaningful." He will likely re-categorize the drug as "off label," as something that may help many people, but something the government just doesn't think is worth its price.

Imagine if Dr. Pazdur had to make that statement on the National Mall during the Komen Foundation Race for the Cure, if he had to stand before that crowd and say "It's just not worth it, ladies. The benefits aren't clinically meaningful!" I think Dr. Pazdur would have to be the fastest runner that day.

When the FDA takes something "off label," it is actually rationing treatment. It essentially gives Medicare and most insurance companies permission and justification to deny coverage for the medication. Thanks to Dr. Pazdur, insurers can say the benefits of the drug aren't "clinically meaningful" and thus save themselves thousands of dollars.

If this change in categorization is made, Stage IV breast-cancer patients who are wealthy will still be able to use Avastin. They will pay $4,000 to $10,000 a month for it. Those who are limited by their income to what their insurance or Medicare will cover will be denied the benefits of a drug that can reduce pain and extend life by as much as six months.

What is six months, with less pain, worth to you, your sister, your mother, your wife? That is a very individual decision. But isn't it one that should be made by a patient and her doctor, not a bureaucrat in Washington? ■