How About a 'Kianna's Law'?

Of all the opinions being expressed about the Terri Schiavo case, the hardest to understand is cynicism about the politics of Congressional intervention. Only phony "federalists" question Washington's competence on matters of fundamental rights. And whether you side with Mrs. Schiavo's parents or husband, it is hard not to be impressed by the spectacle of the nation's highest legislative body convening over the fate of a single person.

> ***The scandal of giving a dying cancer patient a sugar pill.***

No, if our solons have exposed themselves to criticism by taking up the Schiavo case, it should be focused not on their motives but on their inconsistency and lack of proportion. To wit: If Terri Schiavo deserves emergency federal intervention to save her life, people like Kianna Karnes deserve it even more.

The 44-year-old Mrs. Karnes—mother of four and grandmother of one—is not brain-damaged. And the possibility (albeit remote, at this point) exists that she could return to a fully normal life. But she will almost certainly die in the near future as long as the federal government continues to deny her treatment for the kidney cancer that has by now spread throughout her body.

Kianna Karnes

What makes Mrs. Karnes's predicament so depressing is that two different developmental drugs have shown great promise for several years now against this once near-untreatable disease. But not only has the Food and Drug Administration not moved with dispatch to approve the drugs, it has begun imposing new testing requirements that make it all but impossible for their developers—Bayer and Pfizer—to provide them to terminal patients on a "compassionate use" basis.

The problem here is the FDA's unethical—and let us stress, *unscientific*—insistence on gathering information about drugs by way of "blinded" placebo-controlled trials, in which a subset of study patients are knowingly denied the new treatment and in some cases denied access to any active treatment at all. This may be moral with an antihistamine; it's certainly not with treatments for a terminal disease. What's more, it's entirely unnecessary. We already know what happens to most cancer patients who don't get treated. They die. We generally know, on average, how long that will take.

So placebo groups are entirely unnecessary to prove significant anti-cancer activity, as the yet-unnamed Bayer (BAY 43-9006) and Pfizer (SU 11248) compounds have already done. Yet the FDA is mandating an unethical placebo trial for the Bayer drug. (The Pfizer drug is at least being tested against another form of care, albeit one that's already all but certain not to work as well.) A deadly follow-on effect of the placebo fetish is that it gives companies a disincentive to run compassionate use programs for unapproved drugs. That's because companies won't be able to satisfy FDA demands to enroll patients in placebo trials if patients know they can get the drug for sure (instead of running the risk of getting a sugar pill) through compassionate use. Hence Mrs. Karnes's deadly predicament.

"If the only alternative is death, then for God's sake let 'em have the drug," says Mrs. Karnes's father, John Rowe, who himself survived leukemia only by getting himself into a clinical trial where he could get another investigational therapy (Gleevec, since approved). Who could disagree?

Well, a few bureaucratic MDs at the FDA do. More specifically, one Richard Pazdur. He is the current head of cancer drugs evaluation at the FDA, and is unfortunately a leading candidate for a new position that would give him the power to thwart the would-be revolution in biotech cancer treatments as well.

Late last year we reported how Dr. Pazdur had undermined—in fact, totally reversed—the meaning of guidelines issued by former Commissioner Mark McClellan intended to speed up drug reviews. His latest attack on the concept of accelerated approval has him demanding that companies enroll patients in placebo-controlled "Phase 3" trials before submitting applications for very promising drugs that should be eligible based on smaller "Phase 2" studies.

A few years back, Dr. Pazdur was the agency's public face in explaining the rejection of Erbitux. That drug has since been approved and become a clinical hit. So has Eloxatin, which the FDA held up for years even after it was approved in Europe but has since become standard care for colon cancer here too.

In almost all recent cases of FDA dawdling, the drugs are proving to be far more beneficial in practice than even the supposed "gold-standard" of placebo trials would have ever suggested. So could someone explain, again, what the benefit is of doing such trials? We're not suggesting Dr. Pazdur is some kind of ogre. But he seems to be more worried about letting drug companies get away with a so-called "race to the bottom" on trial design than he is with getting good drugs to patients. And it's obvious that he can't (or won't) be educated in modern scientific and statistical methods that would allow drugs to be released sooner.

We've never understood why the Republican majority in Washington hasn't been more active on drug-approvals over the past four years. What better way to demonstrate compassionate conservatism and commitment to a "culture of life"? Or to unite the free-market wing of the GOP with the social conservative one? Finally, what better riposte to the left's equation of support for embryonic stem cell research with support for medical progress?

The solution should be non-controversial. We're not talking about potential Vioxxes that will be widely used by generally healthy people. We're talking about treatments for dying patients. So let's have legislation mandating that the FDA grant access to these drugs as soon as they show anti-cancer activity.

Instead of restricted-access placebo trials, drug researchers could be using large, open access trials in which everyone who wants the new drug can get it. They could then take advantage of advanced statistical methods to figure out whether the drug is working. Wall Street traders use these kinds of math tools all the time, and so do economists. So-called Bayesian statistics are already used in medical device regulation, where even the FDA recognizes that randomizing people into sham surgeries is simply beyond the pale.

Well, what about cancer and other terminal patients? They are now dying needlessly in placebo-controlled trials. And would-be patients like Kianna Karnes are dying outside of them because they make "compassionate use" all but impossible. Won't Congress do something?