

OPINION

LETTERS TO THE EDITOR

How Much to Spend on Marginally Effective Medicine?

Mark Thornton demonstrates the emotionalism that adversely influences the approval policies of the FDA on new drugs ("The FDA vs. Bone Cancer Patients," op-ed, May 7). This emotionalism is a boon to drug manufacturers who charge unconscionable amounts for drugs providing little additional benefit to patients, at a tremendous cost to society as a whole.

He says that while the Food and Drug Administration demanded additional study of a unique drug with a novel technology, "80,000 men lost their lives to prostate cancer . . . equal to the number of men killed in combat in the Korean, Vietnam and Iraq wars combined."

He then points out that "Those FDA staffers who had a role in preventing the approval of Provenge in 2007 will have to live with this sin of omission." But what he fails to mention is the actual value of this technology.

Provenge will cost about \$90,000 to \$100,000 per treatment and will add about four months of life, on the average, to the population of patients who receive it. It is considered a palliative medicine, not a cure.

Therefore, in that three-year period Dr. Thornton cites, the 80,000 patients would still have died, only

four months later at a cost to society of \$8 billion.

I do not know if Dr. Thornton will lose much sleep over this issue, though he should if he is concerned about how the money could have been better spent.

The FDA is still influenced by political issues and not purely scientific ones. Its approval of this drug, as well as other agents of marginal efficacy in terminal disease such as pancreatic cancer, is evidence of this.

Progress in our war on cancer comes in small, incremental steps. Small advances at tremendous cost, claimed as major victories, may exhaust the warriors before true victory can be achieved.

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Dr. Thornton highlights the absurdity of requiring trials of investigational agents to enroll as many subjects (called the sample size) as there are patients with the disease (the target population). Computing sample size using the dominant statistical "frequentist" paradigm does not consider the number of patients in the target population. This method could paradoxically require more patients in the study than exist in the target population.

For many years (centuries

in fact), Bayesian techniques have existed that can compute sample size, taking into account the size of the target population and other policy-relevant factors, such as the consequences in lives lost, patient well-being and the economic costs of making a wrong policy based on the trial findings. Successful applications of these techniques have been used in medicine over the past 20 years. Moving from a dominant culture—the overuse of statistical methods that are not sufficiently robust for the problem at hand—takes patience and persistence. Hopefully, the FDA will take this opportunity to explore new techniques, even if they are centuries old.

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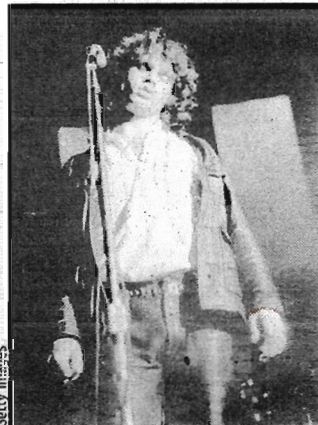
Provenge's side effects include additional pain and suffering, such as fever and chills in most patients, more severe side-effects in a quarter, and even stroke in a handful of them.

It is the duty of the FDA to ensure safety and effectiveness prior to approval of new medical drugs and devices and it should be applauded for doing this job carefully.

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Morrison Was the Reality TV of His Conservative Era

Nancy deWolf Smith is correct that Jim Morrison's antics now look just plain silly ("Does He Still Light Your Fire?," Television, May 7). But you had to be there. Mid-to-late 1960s American society and entertainment were, by today's standards, quite conservative. Openly conservative Frank Sinatra and Bob Hope were major celebrities. It's hard to imagine today that there was a time when reality TV programs showing every make and manner of human stupidity and crassness did



Jim Morrison

Popular culture lurches from extreme to extreme, with each "advance" eventually settling into banality or just plain irrelevancy. Look at the impact "modern" composers like Igor Stravinsky had on society at the beginning of the 20th century. His music caused rioting. And before him Richard Wagner in the late 19th century scandalized Europe. Yet both of these men are regarded as stodgy, old dead white guys by today's youth. And now, we move on to the next fad.

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