

Good Morning,

This is an editorial from this morning's New York Times that discusses the problem and a government proposed solution, in part, to the rapidly escalating costs for chemotherapy and potential conflicts of interest with recognized drug compendia such as the American Hospital Formulary Service – Drug Information (AHFS – DI) as the source of information for reimbursing for the off-label use of cancer drugs.

In previous Drugs in the News the question was raised if these compendia, including the AHFS-DI, can any longer be considered unbiased and authoritative. This editorial raises the same question.

Best,

**The New York Times**

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Editorial

## **Medicare and ‘Off-Label’ Cancer Drugs**

The use of cancer drugs is expanding, and the price is soaring — some individual drugs cost thousands of dollars a month. To the extent that patients benefit, the expense is often justified. But there are worries that the nation is spending much more than is warranted.

Fortunately, the Obama administration seems ready to eliminate laws, policies or conflicts of interest that may be driving up costs unnecessarily. It needs to take a close look at a Medicare rule adopted in November that seems likely to make the cost problem worse by expanding coverage for “off-label” uses of cancer drugs — uses other than those for which the drugs have been specifically approved by the Food and Drug Administration.

As recently described by Reed Abelson and Andrew Pollack in The Times, the rule does so by increasing the number of reference guides — or compendiums — that Medicare relies on to determine which off-label uses to cover. Medicare officials insist they aren't required to pay for a drug simply because it is recommended in a compendium. But many experts say that the practical effect is to virtually guarantee that Medicare pays for the off-label use.

That might be fine if one could be confident that the compendiums were authoritative and unbiased, but analysts have found that compendium recommendations are often supported by little clinical evidence and are written by experts with financial ties to the drug industry.

Off-label uses are vitally important in cancer care and probably constitute a majority of cancer drug treatments. But the danger in expanding usage without strong evidence of safety and effectiveness is that patients may be harmed — and costs may be driven up unnecessarily.

The cost problem is exacerbated because Medicare appears to be legally constrained in what it can do to rein in spending. An article in the *New England Journal of Medicine* by Peter Bach, a cancer expert, contends that laws and regulations shield cancer drugs from strategies used by insurers to hold down costs, such as concluding that various drugs are interchangeable and driving users to comparable cheaper drugs.

The solution — and an essential component of health care reform — is to establish centers for comparing the effectiveness of drugs and treatments and the cost-effectiveness of using them. That would help make coverage decisions more rational for all patients.