Lowering the High Cost of Cancer Drugs—I

To the Editor: In the August 2015 issue of *Mayo Clinic Proceedings*, the article by Tefferi et al[1] on the high cost of cancer drugs left many issues unaddressed or underaddressed.

First, the article could have questioned how the big pharmaceutical companies have always obtained drug prices that are not related to the true research and development costs, these costs being inferior to the marketing one.[2]

Second, the claim that "The good news is that effective new cancer therapies are being developed by pharmaceutical and biotechnology companies at a faster rate than ever before"[1] is far from evidence based. Easy-ride regulators are failing to compare new with current effective therapy using designs that are methodologically rigorous, and the use of surrogate end points replaces evidence with hope.[3,4]

Drug prices are not related to their therapeutic value. This is a general issue, not specific to cancer drugs. Under current pricing, noninnovative "me-too" drugs are priced as high or higher than older drugs, without being more effective. The system has artificially increased the incentives for developing noninnovative me-too drugs rather than innovative medicines for unmet needs.[5] As a result, in 2013, spending on specialty drugs, a category dominated by cancer drugs, totaled $73 billion. That year, 8 new cancer drugs were approved by the US Food and Drug Administration. The Medicare price, which includes patient coinsurance, for these 8 drugs ranged from $7000 to $12,000 per month, with some agents producing overall survival improvement of nearly 6 months and others producing no improvement in overall survival.[6]

Last, the 30th World Oncology Forum convened by the European School of Oncology in 2012 with the task of evaluating progress to date in the war against cancer concluded that current strategies for controlling cancer are clearly not working. It issued a remarkable action plan that was concise: there were only 10 actions, with the war on tobacco being first.[7]

As Albert Einstein said, "Problems cannot be solved with the same mind set that created them." We need innovative solutions if drug pricing is to become more appropriate and affordable.

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Lowering the High Cost of Cancer Drugs—II

To the Editor: We read with interest the article by Kantarjian and Rajkumar[1] in the April 2015 issue of *Mayo Clinic Proceedings* in which the authors explored the main controversies surrounding the pricing of new innovative drugs, particularly drugs used in oncology and hepatology. Subsequently, in the August 2015 issue of the *Proceedings*, Tefferi and more than 100 cancer-specialist coauthors[2] addressed the same issue by emphasizing that cancer patients' out-of-pocket expenses have dramatically increased over the past few years and that these price increases are unsustainable.

Although different strategies to reduce drug prices and subsequently improve patients' adherence in using prescribed drugs were discussed in these 2 articles, one recent procurement tool—the price-volume agreement—was not mentioned by these authors, even though some experience has already accumulated with this tool, particularly in Europe.

In managing drug prices at the national level, price-volume agreements represent a procurement tool that markedly improves drug affordability by patients when the drug price is initially high but the treated patient population expands and becomes large. Specifically, these agreements determine a progressive price reduction as more and more patients are treated. Price reductions have generally been based on empirical data (eg, what is the cost of the recently introduced drug and how many patients are taking it?), but a theoretical basis for determining price may also be beneficial.[3-5]

We analyzed the price-volume agreement that the Italian Medicine Agency negotiated with the manufacturer of sofosbuvir, a nucleotide analogue drug used to manage hepatitis C virus infection. The price-volume agreement made in Italy is confidential,[5] but some information has been reported in the media (the data presented herein are based on references from the Italian Medicine Agency website[6] and from Quotidiano La