For What It's Worth

"There's something happening here / What it is ain't exactly clear."
—*Stephen Stills*

"For What It's Worth," the well-known protest song that begins with the lyrics above, was recorded by Buffalo Springfield in 1966. And protesting we are once again, in various guises. From a letter from more than 100 oncologists (including yours truly) in the August issue of the *Mayo Clinic Proceedings* to the political platforms of Hillary Clinton and Bernie Sanders, it has become commonplace to criticize drug companies for their high prices. The poster child (emphasis on the word *child*) for pharmaceutical misbehavior has been Martin Shkreli, the chief executive officer of Turing Pharmaceuticals who raised the price of pyrimethamine by more than 50-fold.

Cancer care costs are expected to increase from $125 billion in 2010 to $158 billion in 2020, according to the National Cancer Institute. Some potential fixes include permitting Medicare to negotiate prices with pharmaceutical companies, facilitating the approval of generics, and limiting out-of-pocket costs for patients. The August 10 edition of the *Journal of Clinical Oncology* contained a "conceptual framework" from the American Society of Clinical Oncology (ASCO) to assist oncologists and their patients in making decisions regarding the value of a specific treatment in an individual patient. According to ASCO's Value in Cancer Care Task Force, cost should reflect clinical benefit. The Task Force determines value in cancer care based on 3 critical elements: clinical benefit (efficacy), toxicity (safety), and cost (efficiency). Their recommendations rely largely on 2 metrics. The first metric is quality-adjusted life-year (QALY), a measure of disease burden reflected in the quality and quantity of life. A drug with a low cost-to-QALY ratio would be more favorable than one with a higher ratio. The second metric is the incremental cost-effectiveness ratio, which reflects the incremental cost per QALY. A particular therapy receives a certain number of points for efficacy and low toxicity, with bonus points for palliation, to a maximum of 100 points for curative treatment. The sum of these is the Net Health Benefit score. The patient's drug cost is then factored in and, voilà, you can discuss the cost-to-benefit ratio with your patient.

This framework is still evolving, and an app is certainly in development. I assume the physician caring for an individual patient will have to know the results with a particular regimen (or at least have the time to search for them online or perhaps within the app) to calculate the points, and will have to look up its cost. The cost will clearly change over time as drugs come off patent and generics or biosimilars become available. Efficacy will also change as molecular and genetic subsets are identified that are more or less likely to respond to a particular treatment.

Although I admire the effort put into developing this value framework, there are a number of problems that can be anticipated, and others that may be unforeseen.

Such a calculation will clearly assist patients in determining how much a treatment will drain their pockets. Some treatments are clearly worth every penny, whereas others should not see the light of day. Even when the value of a particular treatment has been demonstrated in a clinical trial, is it clearly applicable to the patient at hand? Where is the line of demarcation in the gray zone? If a patient has the resources, what is the least benefit or greatest adverse effect that would be considered tolerable? There are other factors that are harder to quantify: oral medications that are much more expensive than older intravenous drugs, but without the hours spent in the infusion chair and loss of work hours. And, of course, how much additional time will these factors add to a clinic visit, on top of what is already spent by physicians on electronic medical record keeping, further limiting the number of patients a physician would be able to see in an already overbooked clinic day?

We must commend ASCO and its team for taking on this issue. Obviously a lot of thought and effort has gone into the framework. Yet there is still much to be done. Reducing prices, assessing value, considering clinical trials, and not treating the untreatable will all help bring sanity back to the cost of oncology care.

Until next month . . .

Bruce D. Cheson, MD