How to Fix Cancer Drug Shortages

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We were on Capitol Hill last week, joined by Mark Thompson, MD, an oncologist from Columbus, Ohio, discussing cancer drug shortages with members of Congress and their staff. After researching the problem and testifying to Congress on the crisis (as we related in previous commentaries), we have focused on solutions. Although the drug shortage crisis is a complex problem, if you analyze the market dynamics and issues, the solutions become apparent. The task is to communicate them to Congress and overcome the political divide, which is especially evident during an increasingly heated election year.

Repeat after us—it’s all about basic economics

As we related in a previous commentary, the drug shortage crisis is very complicated; however, the root cause is not. The problem is grounded in economics and goes back to the way that Medicare reimbursement for cancer care was changed in the Medicare Modernization Act of 2003. The reason for the change was well-intended — better balance between Medicare payment for drugs and services and market rates. However, the policy change, exacerbated by poor implementation on the part of the Centers for Medicare & Medicaid Services (CMS), has had unintended consequences. The first consequence has been a consolidation of oncology providers, including clinic closings and mergers into large hospital systems. The second is a severe reduction in the number of manufacturers supplying low-cost, generic cancer drugs.

The Medicare reimbursement system has created price controls for cancer drugs. It has put a ceiling on price increases while maintaining no floor on how low prices can fall. This has caused prices for low-cost, injectable generic cancer drugs to fall significantly. Prices for the top drugs in short supply that we analyzed have fallen an average of 50% from 2005 through 2011, and that did not include certain discounts and rebates that manufacturers are required to pass on to providers (340b institutions) and governments (Medicaid). As a result, the net average drop in price was much greater than the 50%.

We are not taking the position of generic manufacturers; but, when these drugs drop to $1 to $2 per vial, one is hard pressed to understand how any manufacturer can stay in business producing products with such low financial return. Consider also that these are not simply pills, but are drugs that have to be manufactured according to exacting, sterile specifications. One also has to question how these low-priced drugs provide the capital for manufacturers to reinvest in upgrading their production facilities.
**Solutions start with economics**

Simply put, the pricing for injectable generics has to be stabilized. We believe that moving from the current Medicare reimbursement system based on average sales price (ASP) to one using wholesale acquisition cost (WAC) is a necessary, critical step to fixing the problem. WAC is a contract price established by the manufacturer to wholesaler, rather than ASP, which is a fluctuating price. WAC has the benefit of being a current price that would not be capped in the context of reimbursement. As such, it would bring stability to market pricing, while allowing price changes up or down based on market dynamics. Using a weighted WAC would create more market stability by softening any extreme pricing moves. In using WAC, there would have to be a “holiday,” or moratorium, from discounts and rebates that pull prices down.

At the same time, the FDA has to be pushed to accelerate plant inspections and drug approvals for new generic entrants. Streamlining processes at the FDA would likely have the most immediate impact on increasing production output; however, this cannot be the sole solution. Not fixing the pricing problem will leave the market imbalanced. Pricing and regulatory solutions are needed in tandem to stop this growing crisis.

**A fix lies with Congress**

Unfortunately, Congress must pass legislation to implement these solutions, especially a change in market pricing for generic injectable drugs. In a year when political tensions are ratcheting up as we move closer to the elections, the prospect of meaningful legislation appears remote. That is why the Community Oncology Alliance (COA) has been asking all impacted to call their Representatives and Senators, and why we have been very active on Capitol Hill. As seen in legislation already in play, some believe that requiring generic manufacturers to warn early when they are shutting down production is a solution. Although this would be useful information, it will not fix the economic cause of the shortages—it is merely treating the symptoms of the underlying problem.

We found members of Congress to be very aware of the crisis and interested in understanding solutions because they are hearing from constituents. So, if you want to help be part of the solution to the drug shortage crisis, contact your members of Congress. The more that Congress hears about how the crisis is adversely impacting cancer treatment and clinical research, the more likely that meaningful legislation with real solutions will be advanced.