Testimony on:

Drug Shortages Crisis

United States House of Representatives

Committee on Oversight and Government Reform

Subcommittee on Health Care, District of Columbia, Census, and the National Archives

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November 27, 2011

The opinions expressed in this testimony are mine and were prepared by me with input from David Eagle, MD and Patrick Cobb, MD.

Chairman Gowdy, Ranking Member Davis, and members of the committee — I thank you for the opportunity to share my views on the drug shortages crisis relating to cancer care.

I am not a medical oncologist but serve as the Executive Director of the Community Oncology Alliance (COA), a non-profit organization dedicated to community cancer care. In my position, I hear from cancer patients and their providers how treatment has to be delayed, changed, and in cases stopped because low-cost, but potentially life-saving generic infusible cancer drugs are not available. Escaping the crisis is next to impossible as my wife is an oncology nurse who voices the frustrations of all cancer care providers when she asks, "How can this be happening in the United States?"

The drug shortage situation 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 (MMA). The reason for the change was well intended — better balance Medicare payment for drugs and services to market rates. However, the policy change, exacerbated by poor implementation, 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.

Let me briefly explain the evolution of drug shortages.

The MMA changed Medicare Part B drug reimbursement from average wholesale price (AWP) set by the manufacturer to average sales price (ASP), a market-based price. Oncology clinics administering chemotherapy are reimbursed by Medicare at ASP plus 6%, which is intended to cover drug cost, overhead, staff, and materials. In actuality, reimbursement is lower than ASP plus 6% due to manufacturer-to-distributor prompt payment discounts included in the ASP calculation. It is also important to understand there is a perpetual lag of 6 months in updating ASPs each quarter, which results in providers subsidizing Medicare for drug price increases.

There are two key points to note about the ASP reimbursement system.

First, the system substantially reduced Medicare provider payments for cancer drugs. However, CMS (the Centers for Medicare & Medicaid Services) never balanced this shortfall by increasing payment for non-reimbursed, essential services such as treatment planning. Instead, CMS put in place two demonstration projects in 2005 and 2006 to provide stopgap funding for the shortfall in services payments. A study by Avalere Health found that by 2008 Medicare covered only 57% of the cost for just the services associated with chemotherapy infusion. The overall shortfall in Medicare reimbursement has forced community clinics to close — 199 over a 3½-year period — and an increase in mergers of clinics into hospitals — 315 over the same time period.

Second, the AWP-based reimbursement system allowed generic drug manufacturers to compete on the margins they established by setting a drug's AWP and then selling the drug at a discounted price. The ASP-based system changed the generic drug manufacturers' means of competing to solely on actual sales price. That and the 6-month lag in updating Medicare reimbursement rates has resulted in a system that is effectively price capped. There has been steady downward pricing pressure on most generics since 2005, the year ASP was first implemented. For some of the top cancer drugs in short supply the ASPs have dropped approximately 50% since 2005. You should also understand that ASP masks the true decline in prices for manufacturers because they do not reflect other discounts and rebates exempt from the calculation of ASP. Generic manufacturers have felt additional pricing pressure from an increasing volume of 340B discounts, which they are required to extend to 340B-eligible hospitals and other institutions treating a disproportionate share of low-income and uninsured patients. As more oncology practices under reimbursement pressures have been acquired by hospitals eligible for 340B pricing, the volume of these discounts have increased. Furthermore, Medicaid rebates exert further downward pricing pressure on manufacturers.

Although, on the surface, declining prices are a positive for payers and patients, the problem is that many generics have reached severely low prices. Consider if manufacturing a $1 sterile infusible cancer drug is economically viable in the long run. In a market that is highly regulated, both in terms of pricing and manufacturing, normal market forces are not in effect. Faced with the prospect of diminishing returns from low-priced, discounted, and rebated drugs, the incentive to stay in the market is reduced. This has led to fewer manufacturers producing these products. As a result, any manufacturing, regulatory, or quality problem that shuts down a production line has a magnified impact on the supply of product.

In closing, I implore the Congress to work with the cancer community in fixing this growing crisis. Next month will mark the forty-year anniversary of when our nation declared war on cancer. We have evolved our cancer care delivery system into the best in the world, as documented by survival. Americans battling cancer today and for generations to come should have access to quality, accessible and affordable cancer care. We stand ready to provide you with supporting data and to work on immediate solutions.

Thank you for listening.