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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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.

Theodore A. Okon
Biography/CV

Ted Okon began his career over 25 years ago in the healthcare industry. In the early years of his career, he worked for several major healthcare companies, including Warner-Lambert/Parke Davis and Co. (now part of Pfizer, Inc.), Merck, Inc., and IMS America, in a variety of marketing and management positions.

His interest in developing more accurate and practical healthcare information led Ted to co-found Medical Marketing Group, Inc. (MMG), a company that pioneered the use of sophisticated databases to provide utilization patterns on prescription pharmaceuticals. Ted served as President of MMG. First a private company, MMG became majority owned by Medco Containment Services, Inc., a leading drug benefit manager. MMG was instrumental in helping Medco change its passive drug distribution business to a value-added, cost containment model. MMG was spun out and taken public in what was the second most successful public offering of the year. MMG was subsequently purchased as part of the merger of Merck and Medco.

Following that, Ted added to his experience by working with healthcare professionals from oncology practices around the country. This specifically involved the application of information technology to improve information, collected from and provided to patients at the point-of-care in order to improve clinical outcomes; develop disease management approaches; and building a new model for clinical research, a very inefficient and labor-intensive process. These initiatives resulted in Ted collaborating with two oncologists from the West Clinic, Drs. Lee Schwartzberg and Kurt Tauer, in founding two companies: Accelerated Community Oncology Research Network, Inc. (ACORN) and Supportive Oncology Services, Inc. (SOS). Ted served as CEO of ACORN and SOS.

While leading ACORN and SOS, Ted founded Cancer Clinics of Excellence (CCE), which is an association of community cancer clinics dedicated to working together to clinically integrate and to create outcome measures. Ted led the development of a new disease management model for oncology based on evidence-based treatment protocols.

Additionally, Ted has first-hand experience with cancer care delivery systems throughout the world. He has traveled extensively to the United Kingdom, India, China, Singapore, and the Middle East to understand their existing cancer care delivery systems and to assess interests of bringing American cancer care to those rapidly growing parts of the world.

Ted currently serves as Executive Director of the *Community Oncology Alliance* (COA). The mission of COA, which is a nonprofit organization, is to protect and foster the cancer care delivery system. COA was created by oncologists to advance the cancer care delivery system for their patients. Ted works with oncology practices on educational initiatives and studies to increase the quality and efficiency of cancer care delivery. He also spends time on Capitol Hill, where he relies on his experience and knowledge of the clinical and operational aspects of cancer care delivery to provide information and to advocate for community oncology. Ted directs the overall strategy of COA that is overseen by its Board of Directors and Executive Committee. In carrying out his advocacy role, Ted is a registered lobbyist.

In addition to general management experience and political knowledge, Ted has specific expertise in health care information, clinical outcomes measures, drug distribution, and disease management. Ted has in-depth knowledge of the reimbursement for cancer care drugs/services and the trends changing the way cancer is treated. Ted is frequently asked to speak to state oncology societies, managed care organizations, and others interested in understanding the trends in oncology, especially relating to health care reform, reimbursement issues, drug shortages, politics and public policy. He has authored numerous

studies and articles relating to clinical and reimbursement issues, as well as the politics of health care reform and cancer care.

Ted holds a BS degree in biology from Fairfield University and an MBA from Carnegie-Mellon University. He resides in Connecticut with his wife Susan, who is an oncology nurse in full-time practice. His daughter, Katherine, is pursuing an MBA at the Darden School of Business at the University of Virginia.