

Good morning! My name is Walter Kalmans, and I am currently employed as Vice President of New Ventures at WhiteGlove Health, a venture-backed company in Austin, TX. This testimony is not related in any way to my current employer. Rather, it is based on work independently developed as a result of 20 years of experience working as a consultant and commercial operations executive in the pharmaceutical industry.

Of particular relevance to this hearing is experience gained while serving as Vice President of Business Development for Oncology Therapeutics Network (OTN) from 2003 to 2008. OTN was the 2<sup>nd</sup> largest specialty drug distributor in the United States until its acquisition by McKesson Corporation in late 2007.

The popular press as well as recent publications by ASPE, FDA, and IMS Health do a good job characterizing the generic drug shortages and tend to cite manufacturing and supply chain issues as the chief culprits. As citizens, we are led to believe that over time, industry will fix the problem by investing in additional capacity, improving quality control, and identifying more high-quality suppliers for raw materials.

However, there is much more to this issue. Why all of the sudden would the pharmaceutical industry, one of the most sophisticated industries on Earth, be experiencing an unprecedented growth of shortages, and why in particular, shortages of generic injectable drugs? Manufacturing and supply chain issues certainly play a role, but it is my opinion that the Medicare Modernization Act (MMA) of 2003 is the core culprit for why generic injectable drugs are in growing shortage.

To most Americans, MMA is known as the act that expanded prescription drug coverage for Medicare patients; however, another part of the legislation drastically altered how Medicare reimburses community-based oncologists who administer drugs in their offices, under Medicare Part B. Oncologists are one of the few specialists who make a margin on buying a drug for price X and receiving Medicare reimbursement of price X+Y.

Prior to MMA, Medicare reimbursed community-based oncologists based on a price called AWP (average wholesale price). MMA introduced a new price called ASP (average selling price). Calculating ASP required significant pricing transparency from pharmaceutical manufacturers and resulted in lower Medicare reimbursement payments to community-based oncologists and notably, a more rapid price decline for many generic injectable drugs.

In addition, because the legislation set Medicare reimbursement for Part B drugs at ASP+6%, it established thinly veiled price controls making it unpalatable for a pharmaceutical manufacturer to raise price more than 6% a year. For example, if a

manufacturer were to raise price on a \$100 drug more than 6% during a year, an oncologist would likely be faced with the scenario of buying the drug for \$106 and receiving Medicare reimbursement of \$104.

Now fast-forward to today, if you were a generic injectable manufacturer with finite capacity, would you focus your capacity on manufacturing generics for products that have just lost patent protection, reaping high profits for the next few quarters, or would you manufacture lower priced generics, drugs whose patents expired long ago?

Under normal economic circumstances, if there are shortages, prices adjust upward to reach a new equilibrium until additional product comes on-line. However, because MMA limits price increase to 6% annually, prices do not reach an equilibrium; even worse, because the profit potential of these drugs is so low, new entrants decide to stand on the sidelines or focus on more profitable products.

In conclusion, it is my opinion that we will experience shortages of generic injectable drugs until legislation is passed to change the way generic injectable drugs are reimbursed by Medicare. Like any piece of legislation, MMA provided many citizens with benefits, but also like any piece of legislation, it had flaws. Unfortunately, these flaws took several years to be exposed and for a variety of reasons, it may take quite some time to fix them.

Thank you!